Oxford Immunotec Global PLC
Form 10-K
March 28, 2019

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

FORM 10-K

(Mark One)

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number 001-36200

OXFORD IMMUNOTEC GLOBAL PLC

(Exact name of registrant as specified in its charter)

England and Wales	**98-1133710**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
94C Innovation Drive, Milton Park, Abingdon OX14 4RZ, United Kingdom	**Not Applicable**

(Address of Principal Executive Offices) (Zip Code)
+44 (0)1235 442780

(Registrant's Telephone Number, Including Area Code)

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

Title of each class	**Name of exchange on which registered**
Ordinary Shares, £0.006705 nominal value per share	**The NASDAQ Global Market**

Securities registered pursuant to Section 12(g) of the Act

None

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes No

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

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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 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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer Accelerated filer Smaller reporting company

Non-accelerated filer Emerging growth company

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

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

As of March 1, 2019, there were 26,617,311 Ordinary Shares, nominal value £0.006705, of Oxford Immunotec Global PLC outstanding.

As of June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's Ordinary Shares held by non-affiliates was approximately $283,039,200.

DOCUMENTS INCORPORATED BY REFERENCE

The following documents (or parts thereof) are incorporated by reference into the following parts of this Form 10-K: Certain information required by Part III of this Annual Report on Form 10-K is incorporated from our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2018.

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K, and exhibits hereto, contains or incorporates by reference estimates, predictions, opinions, projections and other statements that may be interpreted as "forward-looking statements" within the meaning of Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. The forward-looking statements are contained principally in Part I, Item 1: "Business," Part I, Item 1A: "Risk Factors," and Part II, Item 7: "Management's Discussion and Analysis of Financial Condition and Results of Operations," but are also contained elsewhere in this Annual Report. In some cases, you can identify forward-looking statements by the words "may," "might," "will," "would," "could," "should," "intend," "plan," "contemplate," "expect," "anticipate," "believe," "estimate," "pr "target," "potential," "continue," and "ongoing" and other comparable expressions intended to identify statements about the future, although not all forward-looking statements contain these identifying words. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, level of activity, performance or achievements to differ materially from those currently anticipated. Forward-looking statements are neither historical facts nor assurances of future performance. Although we believe that we have a reasonable basis for each forward-looking statement contained in this Annual Report, we caution you that these statements are based on a combination of facts and factors currently known by us and our expectations of the future, about which we cannot be certain and that involve substantial risks and uncertainties. Such risks and uncertainties include, but are not limited to:

- our failure to meet our obligations arising from the sale of our U.S. laboratory services business, or the U.S. Laboratory Services Business, with Quest Diagnostics Incorporated, or Quest, a Delaware corporation, or the Transaction;
- the potential disruption of management time from ongoing business operations due to the Transaction;
- our exposure to potential litigation and contingent liabilities pursuant to the Transaction that could have a material adverse effect on our financial condition;
- our history of losses, our ability to achieve or sustain profitability and our ability to manage our growth;
- our ability to effectively use our current financial resources and our ability to obtain additional capital resources;
- our ability to further develop, commercialize and achieve market acceptance of our current and future products;
- our ability to obtain and maintain regulatory body clearance and approval to market any of our products;

continued demand for diagnostic products for tuberculosis, tick-borne diseases and other than immune-regulated conditions and the development of new market opportunities;

our ability to compete successfully and to maintain and expand our sales network;

coverage and reimbursement decisions of third-party payors, as well as guidelines, recommendations, and studies published by various organizations related to the use of our products;

decisions by insurers and other third party payors with respect to coverage and reimbursement for our products;

our dependence on certain of our customers, suppliers and service providers;

disruptions to our business, including disruptions at our laboratories and manufacturing facilities;

the integrity and uninterrupted operation of our information technology and storage systems;

the impact of currency fluctuations on our business;

the impact of global economic and political developments, including the referendum to leave the European Union, passed by the United Kingdom, or U.K., on June 23, 2016, and further implementing legislation on our business;

potential changes in the United States, or U.S., social, political, regulatory and economic conditions or laws and policies governing the health care system, U.S. tax laws, foreign trade, immigration, manufacturing, and development and investment in the territories and countries where we or our customers and suppliers operate;

our ability to make successful acquisitions or investments and to manage the integration of such acquisitions or investments;

our ability to retain key members of our management;

the impact of taxes on our business, including our ability to use net operating losses;

the impact of legislative and regulatory developments, including healthcare and tax reform, on our business;

the impact of product liability, intellectual property and commercial litigation on our business;

our ability to comply with Securities and Exchange Commission, or SEC, reporting, antifraud, anti-corruption, environmental, health and safety laws and regulations;

our ability to maintain our licenses to sell our products around the world, including in countries such as China and the U.S. and in the several U.S. states requiring licensure;

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our ability to protect and enforce our intellectual property rights;

our status as an English company listing ordinary shares in the U.S.;

the volatility of the price of our ordinary shares, including the risk the Transaction could have adverse effects on the market price of our ordinary shares, substantial future sales of our ordinary shares and the fact that we do not pay dividends; and

the impact of anti-takeover provisions under U.K. law and our articles of association.

You should refer to Item 1A, “Risk Factors” in this Annual Report for a discussion of other 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. Further, 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 that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views only as of the date of this Annual Report. Subsequent events and developments may cause our views to change. While we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report. As used in this Annual Report, the words “Company,” “we,” “us” and “our” refer to Oxford Immunotec Global PLC, a public limited company incorporated under the laws of England and Wales.

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Part I

Item 1. Business

Overview

We are a global, high-growth diagnostics company focused on developing and commercializing proprietary tests for immunology and infectious disease by leveraging the technological, product development, manufacturing, quality, regulatory, and sales and marketing capabilities we have developed over our sixteen year history. Our proprietary T-SPOT®[1].*TB* test utilizes our T-SPOT technology platform to test for tuberculosis, which is the leading cause of infectious disease death worldwide.

On November 6, 2018, we completed the sale of our U.S. Laboratory Services Business to Quest, for gross proceeds of $170 million in cash. This Transaction represented a strategic business shift and it had a major effect on our operations and financial results. Following the Transaction, we have approximately 210 employees, including sales and marketing teams on three continents, and a laboratory in the United Kingdom.

Our T-SPOT.*TB* test

Tuberculosis is a common and, if not properly treated, potentially lethal infectious disease caused by the bacterium *Mycobacterium tuberculosis*, or MTB. MTB typically infects the lungs, but the lymph nodes, kidneys, brain and bones may also be infected. Those with latent tuberculosis infection, or LTBI, are asymptomatic and are not infectious; however, each person with LTBI has a 5% to 10% chance, on average, of progressing to active TB over his or her lifetime. This risk of progression to active TB is significantly elevated among individuals with weakened immune systems, such as those with human immunodeficiency virus, or HIV, or diabetes or those on drugs that suppress the immune system (e.g., those taking biologic therapies for autoimmune disease or those undergoing immune suppression post-transplantation). Without proper treatment, up to two thirds of individuals with active TB disease will die.

According to the World Health Organization, or the WHO, approximately 23% of the world's population, or about 1.7 billion people, are infected with *M. tuberculosis*. Despite the availability of an effective treatment, TB is the leading cause of infectious disease death worldwide and remains one of the top ten causes of death worldwide from any cause. The WHO estimated that in 2017 approximately 10 million people developed TB disease, of which approximately

1.6 million people died.

There are three broad strategies to control TB: vaccination, finding and treating active TB disease, and finding and treating LTBI to prevent the development of new active TB disease cases. The United States has one of the most comprehensive LTBI screening programs in the world with screening of several high-risk groups, including healthcare workers, recommended by the U.S. Centers for Disease Control and Prevention, or the CDC. Screening of healthcare workers is also recommended as part of the accreditation standards for U.S. hospitals. Other high-risk groups identified by CDC include persons with immunosuppressive conditions, such as persons receiving immunosuppressive agents or organ transplant recipients, and persons with human immunodeficiency virus, or HIV. In addition, TB screening is required in many cases for additional populations, such as day care staff, school teachers and students, and emergency response personnel.

We estimate that there are approximately 22 million LTBI tests performed each year in the United States, the majority of which are performed within the healthcare system in a variety of settings, including hospitals, public health offices, physicians' offices and clinics. Outside the United States, we estimate the total number of tests exceeds 28 million each year, for a combined market size of over 50 million LTBI tests annually.

The primary test currently used for TB screening is the more than 100-year-old TST. The TST is administered by injecting an extract from cultured *M. tuberculosis*, called tuberculin or PPD, into the skin of a subject's forearm using a needle and syringe. The injection of the PPD into the skin of a subject previously infected with MTB stimulates the immune response, including T cells, causing the formation of a hard lump at the site of the injection. Because it takes time for this reaction to occur, the subject must return 48 to 72 hours after the PPD injection to have the result read. The test result is graded by feeling for the boundaries of the swelling, marking these with a pen and then measuring the diameter with a ruler.

The TST suffers from several limitations, including an antiquated technique that results in substantial test variability, false negative results in immunocompromised patients, false positive results in patients who have been Bacille Calmette-Geurin, or BCG, vaccinated and boosting of results, which occurs when an infected subject's reaction to an initially false-negative TST causes increased sensitivity in a subsequent test such that it tests positive. In addition to these technical drawbacks, the TST requires multiple patient visits, which increases its overall cost.

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[1]"T-SPOT®," "T-Cell Xtend®," "Oxford Diagnostic Laboratories®," "ODL®," "Immunetics®," the Oxford Immunotec logo, our laboratory logo and other marks are our trademarks. Solely for convenience, trademarks and trade names referred to in this Annual Report on Form 10-K, including logos, artwork and other visual displays, may appear without the® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and trade names.

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Our T-SPOT.*TB* test addresses the limitations of the TST by directly measuring antigen-specific T cells indicative of TB infection. We use two TB-specific antigens, ESAT-6 and CFP10, to stimulate T cells that have previously been exposed to MTB, which causes them to release a cytokine called interferon-gamma. Interferon-gamma is one of the dominant cytokines released by activated T cells when encountering MTB. In contrast to the PPD reagent used in the TST, these two antigens are not shared with the BCG vaccine or with most non-tuberculous mycobacteria. Because our test detects individual T cells via their release of interferon-gamma, our test is sometimes referred to generically as an IGRA.

Our proprietary T-SPOT.*TB* test leverages our T-SPOT technology platform, which allows us to measure the response of specific immune cells to inform the diagnosis, prognosis and monitoring of patients with immune-regulated conditions. Our T-SPOT.*TB* test has been approved for sale in over 50 countries, including the United States, where we have received premarket approval, or PMA, from the Food and Drug Administration, or FDA, in Europe, where we have obtained a CE mark, as well as in Japan and China. An interferon-gamma release assay, or IGRA, such as our T-SPOT.*TB* test has been included in clinical guidelines for TB testing in over 30 countries, including the United States, several European countries, China and Japan. In addition, we have established reimbursement for our test in the United States, as well as a Current Procedural Terminology, or CPT, code that is unique to our test. Outside the United States, we have established reimbursement in several countries where reimbursement applies, including Japan, Switzerland, Germany, France and South Korea. We have also established the cost-effectiveness of our test in several published studies. We believe the annual global market opportunity for our T-SPOT.*TB* test is well in excess of $1 billion, assuming we can largely displace the tuberculin skin test, or TST, in the developed world.

Our T-SPOT.*TB* commercialization strategy

We currently offer our T-SPOT.*TB* test as an *in vitro* diagnostic kit globally, meaning we sell test kits and associated accessories to laboratories that perform the testing themselves. We have also established a clinical testing laboratory in the United Kingdom, where we perform our T-SPOT.*TB* test on samples sent to us by customers. We market our service offering under the name Oxford Diagnostic Laboratories®, or ODL®.

Our test is widely reimbursed both internationally, with reimbursement established in Japan, Switzerland, Germany, France and South Korea, and in the U.S., where we have established a unique CPT code for our test.

We believe that clinical guidelines, which are recommendations issued by national medical societies or public health bodies, are a driving factor in a clinician’s decision to use a specific diagnostic test. IGRAs, such as our T-SPOT.*TB* test have been included in clinical guidelines for TB testing in over 30 countries, including the United States, several European countries, China and Japan. In recent years, the use of IGRAs has been increasingly recommended and our sales and marketing activities will continue to look to exploit these increasingly positive guidelines updates.

In December 2016, a publication titled "Official American Thoracic Society/Infectious Diseases Society of America/Centers for Disease Control and Prevention Clinical Practice Guidelines: Diagnosis of Tuberculosis in Adults and Children" recommended use of IGRAs for testing for TB infection instead of the TST for patients over the age of five who meet the following criteria: 1) are likely to be infected with MTB, 2) have a low or intermediate risk of disease progression, 3) testing for LTBI is warranted, and 4) either have a history of BCG vaccination or are unlikely to return for a second visit to read the TST.

In February 2018, the CDC issued a notification informing the United States Citizenship and Immigration Services that a revised tuberculosis technical instruction would go into effect on October 1, 2018. As of the effective date, when a test for cell-mediated immunity to TB is required, all civil surgeons must use an FDA-approved IGRA test; performing a skin test is no longer allowed.

In June 2018, updated guidelines from the American Academy of Pediatrics, or AAP, were published in the AAP's 2018 Red Book: Report of the Committee on Infectious Diseases, or the Red Book. The Red Book contains a composite summary of current recommendations representing the policy of the AAP on various aspects of infectious diseases and is issued every three years.

The AAP guidelines include specific recommendations for the use of IGRAs, such as our T-SPOT.*TB* test, and the recommended age for IGRA use was lowered from five years to two years in these updated guidelines.

In May 2018, IGRAs, of which our T-SPOT.TB test is one of two available globally, were included in the World Health Organization's first ever List of Essential In Vitro Diagnostics (EDL). The EDL includes the 113 most important tests recommended by the WHO for use at various levels of the health care system. These essential diagnostics satisfy the priority health care needs of the population and were selected with due regard to disease prevalence and public health relevance, evidence of efficacy and accuracy, and comparative cost-effectiveness. 58 of the tests listed are for the detection and diagnosis of a wide range of common conditions, providing an essential package that can form the basis for screening and management of patients. The remaining 55 tests are designed for the detection, diagnosis, and monitoring of WHO key disease areas, for which there is high quality evidence – HIV, tuberculosis (TB), malaria, hepatitis B and C, syphilis and human papilloma virus.

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We believe that these guidelines, and similar national guidelines outside the United States in countries such as China, allow us to access the vast majority of the current TST market and assert the superiority of an IGRA in significant segments of the market.

We currently market our T-SPOT.*TB* test directly in the United States, Northern Europe and Japan. Outside of these territories, we have contracted with distributors who market and sell our test. In countries where we have a direct presence, we use a combination of sales managers, sales representatives, customer service staff and technical experts to interact with clinicians, nurses, administrative staff, laboratories and other groups who are involved in the implementation of TB screening programs. Our goal is to educate these groups about the clinical, operational and economic benefits of switching from the TST to our T-SPOT.*TB* test. Our customer service staff and technical experts are also involved in the practical training of customers to perform and order our T-SPOT.*TB* test as well as providing ongoing customer support. In addition to these teams, we offer a diverse array of marketing programs and services, which include advertising, medical education, attendance at scientific meetings and other awareness-raising activities.

We have been investing in product development initiatives that we believe will increase use of T-SPOT.*TB* by new and existing customers, enable TB testing in new locations and create more formidable barriers to entry within the LTBI testing market long-term. For example, in April 2018, we obtained a CE mark for the T-Cell *Select*™ kit, which can be used to isolate mononuclear immune cells using positive selection via a magnetic bead cell separation system. Expected benefits of T-Cell *Select* include simplified workflow, improved throughput, reduced hands-on time and reduced labor costs in performing T-SPOT.*TB*. Furthermore, with T-Cell *Select*, blood samples can be collected in a single standard blood tube and stored for up to 54 hours at room temperature before use in the test, further extending our simplicity and logistics advantages for customers.

We also have a number of capabilities that we believe we can leverage in developing and commercializing products. We have a proven track record of running multi-center clinical trials, changing guidelines and establishing reimbursement, capabilities that are important to commercial success of diagnostic products. We have the experience and capability to gain regulatory clearance to manufacture and sell products meeting the regulatory requirements of numerous countries around the world. This, combined with our global sales and marketing infrastructure, which includes sales and marketing teams on three continents, and a laboratory in the United Kingdom allows us to generate revenues in a large number of countries. Our current customer base includes hospitals, commercial testing laboratories, importers and distributors.

T-SPOT.*TB* regulatory approvals and clinical validation

Our T-SPOT.*TB* test is approved for commercial sale in over 50 countries. Key geographies where we have regulatory approval include:

The United States. We obtained PMA for our T-SPOT.*TB* test from the FDA in 2008. Since 2008, an additional ten PMA supplements have been approved, including supplements relating to manufacturing improvements and label extensions, such as those that enable overnight shipment of blood samples.

Europe. We obtained a CE mark in 2004, which allows us to sell our T-SPOT.*TB* test in Europe as well as other countries that accept the CE mark.

China. We obtained initial approval for our T-SPOT.*TB* test from the China Food and Drug Administration, or the CFDA, in 2010. Consistent with CFDA re-registration requirements, we secured re-registration of our test in 2014, which will remain effective until November 2019.

Japan. We obtained approval for our T-SPOT.*TB* test from the Ministry of Health, Labour and Welfare, or MHLW, in 2012.

In addition to being validated in multiple clinical studies, our T-SPOT.*TB* test has also been the subject of nearly 500 peer-reviewed publications in scientific journals including several meta-analyses.

In April 2018, we declared conformity enabling us to attach the CE mark for the T-Cell *Select* kit, which can be used to isolate mononuclear immune cells using positive selection via a magnetic bead cell separation system. In December 2018, we obtained acceptance of the regulatory notification for the T-Cell *Select* kit by the CFDA.

Our T-SPOT technology platform

The human immune system is composed of two principal branches: cellular (T cell) immunity and humoral (B cell and antibody-based) immunity. Through our T-SPOT technology platform we can efficiently measure marker-specific T cell responses at a single cell level and thereby inform the diagnosis, prognosis and monitoring of patients with immune-regulated conditions. We believe these areas are attractive because they involve large patient populations and chronic conditions that present the opportunity for both initial diagnosis and additional testing to monitor the conditions.

We employ a quantitative method to detect antigen-specific cells releasing immune messenger molecules, called cytokines, released by effector T cells. In relation to effector T cells, our technology is designed to selectively measure responses from this subtype of T cells because they are primarily present when active, replicating pathogens are inside the body, as opposed to other T cell subtypes that may be present long after an infection has been cleared from the body. For diagnosis and monitoring applications, it is more relevant to be able to measure the immune response associated with the current infection rather than the immune response associated only with past, cleared exposure.

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Our T-SPOT technology offers many technical advantages including high analytical sensitivity, potential application across multiple diseases and conditions and standardization of white blood cell counts, which makes our technology particularly useful in immunocompromised patients, such as those undergoing transplant surgery or immunosuppressive therapy. We employ proprietary manufacturing processes and protocols designed to cost-effectively and reliably produce key elements of our T-SPOT technology, including the process for coating microtiter plates with cytokine antibodies, such as IFN-*y* antibodies, and our quality control testing procedures.

Competitive landscape

Our T-SPOT.*TB* test competes primarily with the TST. We believe our T-SPOT.*TB* test has a number of compelling advantages that make it a superior alternative to the more than 100-year-old TST, including superior sensitivity and specificity, simplicity of administration and elimination of variability due to subjective interpretation of results. Although the TST is often considered to be inexpensive, as the PPD reagent and other materials used in the test typically cost less than $5 per test, the materials cost is only one element of the total cost involved when conducting a TB screening program or TB control strategy. Substantial costs beyond the materials cost of the TST test include additional costs associated with: (i) false-negatives and false-positives, which risk non-detection and require additional confirmatory tests; (ii) individuals who fail to return within the prescribed period and, therefore, require re-testing; and (iii) implementing and maintaining training programs for healthcare workers who administer and read TST tests.

Several studies have been published investigating the costs or cost-effectiveness of a TB screening program in the healthcare worker setting using the TST and in comparison to our T-SPOT.*TB* test. We believe these studies are informative in demonstrating how expensive the TST actually is to implement and how using our T-SPOT.*TB* test in preference to the TST can be a more cost-effective solution when implementing TB screening programs.

Other than the TST, our principal competitor is the QuantiFERON®2-TB Gold Plus test, or QFN Plus, which was approved for sale in Japan in 2018, the U.S. in 2017 and has been available in Europe since 2016. Early publications suggest similar performance characteristics between QFN Plus and its predecessor.

We have been competing with QFN Plus, or prior versions of this test, since the launch of our T-SPOT.*TB* test in 2004. Based on our experience, we believe that we have several performance advantages over QFN Plus, including:

In our pivotal clinical studies conducted in support of our PMA, T-SPOT.*TB* test results were not impacted by immunocompromised status or immunosuppression. The U.S. package insert for the QFN Plus test notes that the performance of the USA format of the QFN Plus test has not been extensively evaluated with specimens from the following groups of individuals: individuals who have impaired or altered immune functions, individuals younger

than age 17 years, and pregnant women. The package insert also notes that the minimum number of lymphocytes required for a reliable test result has not been established and may also be variable. We believe this is an important differentiating factor in patient populations with weakened immune systems, such as those on biologic therapies, corticosteroid or other immunosuppressive treatments, those with HIV and those undergoing dialysis or organ transplantation.

In the FDA pivotal studies in the United States, our T-SPOT.*TB* test was shown to have sensitivity advantages over the QFN Plus test.

We have also been successful in securing differential reimbursement for T-SPOT.*TB* in certain geographies, including France and the U.S. In the U.S., where we have established a unique CPT code for our test, this differential reimbursement has been maintained even following recent adjustments to the Clinical Lab Fee Schedule based upon the provisions of the Protect Access to Medicare Act, or PAMA. In 2018, The Centers for Medicare & Medicaid Services, or CMS, reimbursement for our test under CPT code 86481 was approximately $100 per test; CMS reimbursement for QFN Plus under CPT code 86480 was approximately $77 per test. Under PAMA, reimbursement for our T-SPOT.*TB* test for the years 2019-2020 will remain unchanged from 2018 rates. In contrast, the reimbursement for QFN Plus will decrease to approximately $62 by 2020.

Other products

Our C6 *Borrelia burgdorferi* (Lyme) ELISA kit, or C6 Lyme ELISA kit, measures Lyme specific antibodies by leveraging a synthetic version of the C6 peptide antigen, a marker specific to *Borrelia burgdorferi*, the causative organism of Lyme disease in the U.S. The test kit is FDA cleared and CE marked in the European Union. The test has been the subject of over 20 peer-reviewed publications.

Our T-SPOT.*CMV* test utilizes our T-SPOT technology platform to measure the strength of a patient's cellular immune response to antigens specific to cytomegalovirus, or CMV, and provides information that may be useful in informing management strategies of patients at risk of CMV infection and disease, such as transplant patients. Our T-SPOT.*CMV* test is CE marked as a kit in the European Union.

Neither test is currently a material source of revenues for the Company.

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[2] QuantiFERON® is a registered trademark of Qiagen N.V.

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Pipeline

We have active development programs to enhance our T-SPOT.*TB* test offering. We are developing multiple product enhancements that aim to improve the clinical utility of our test and improve test workflow and automation. We believe these enhancements will also serve to increase the barriers to entry in both the U.S. and outside the U.S.

Product development activities are inherently uncertain, and there can be no assurance that we will be able to obtain regulatory body clearance to market our products. Delays in obtaining regulatory clearance may allow for increased competition, thereby potentially impacting the successful commercialization of our products. In addition, we may terminate our development efforts with respect to one or more of our products under development at any time, including before or during clinical trials, based upon changed market conditions.

Intellectual property

We seek to secure and maintain protection of the proprietary aspects of our technology platform and of our existing and planned products. We rely on a combination of patents, trademarks, trade secret and other intellectual property laws, and confidentiality, license and invention assignment agreements and other contracts to protect our intellectual property rights. In addition, we have developed substantial knowledge in the field of immunology diagnostics including proprietary methods that we believe provide us with a significant advantage relative to potential competitors.

The intellectual property relating to our T-SPOT.*TB* test that we own or license includes 12 issued U.S. patents and 13 issued patents and one pending patent application in other jurisdictions, as well as registered trademarks, proprietary manufacturing processes and protocols, and proprietary methods directed towards achieving rapid throughput in assay performance.

Our owned and licensed patents

Many of the patent rights we own or in-license have claims directed to the use of ESAT-6 and/or CFP10 to detect *Mycobacterium tuberculosis*. We believe that these are the most important TB-specific antigens and we include peptides from both of these in our T-SPOT.*TB* test. We also believe that using an ELISPOT technique for an IGRA enhances its accuracy and suitability for use in testing individuals with compromised immune systems. Our T-SPOT.*TB* test employs this technique.

Our technology patents contain claims to methods of measuring marker-specific effector T cell responses at a single-cell level to certain peptides of ESAT-6 to diagnose TB infection. In December 2017, as part of the settlement of our patent infringement action, we received a one-time, lump sum payment of $27.5 million from Qiagen Inc., or Qiagen. The settlement agreement included a non-exclusive, royalty-free license to certain of our patents for use in Qiagen's QFN products. See "Legal Proceedings" for more information. These patents expire in late 2019.

The inventions claimed in our patents relating to removal of granulocytes from stored blood samples may also have applications in relation to other diseases, conditions or situations where blood samples cannot be tested soon after the blood draw. This proprietary method is a core part of the T-SPOT technology as it improves the stability of stored blood enabling the overnight shipment of blood samples. The patents covering these inventions expire in 2027 (outside of the U.S.) and 2028 (U.S.).

We also have licensed certain patents related to the detection of antibody-secreting B cells specific for HLA. We also have two patents under license and acquired a patent family application, pending in four territories, relating to additional TB antigens. The expected expiration dates of the licensed patents range from April 2019 to May 2032. We can give no assurance that any of our current or future research and development programs will result in the development and validation of any diagnostic test that leverages any of these patents or patent applications or otherwise.

Our license and assignment agreements

We currently rely upon several license agreements to obtain rights under certain patents that we believe may be necessary to make, use and sell our products. We may in the future rely, at least in part, upon licensing agreements with third parties to obtain patent rights and transfers of technology, information and know-how to enable us to take advantage of research work already completed, including potentially the identification of antigens useful for measuring disease conditions. We believe such licensing arrangements have enabled us, and may in the future enable us, to reduce the amount of time we need to develop and validate new diagnostic tests.

We have royalty obligations under some of our current license agreements that are measured in part based upon our sales levels. Where our royalty obligations are calculated on our net sales, the definition of net sales varies by agreement and typically resulted in a lower effective royalty rate on our service revenue than on sales of our kits. Currently, our aggregate royalty burden for our T-SPOT.*TB* test under all license and assignment agreements, as a percentage of gross product and service revenue, is in the low single digits. Under our license agreements, we may be responsible for paying, or contributing to, patent prosecution and maintenance costs or subject to diligence obligations. We believe we are in compliance with all obligations of our license agreements.

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Tuberculosis related patents

In 2013, we entered into an assignment agreement with Isis Innovation Limited, now known as Oxford University Innovation Ltd., or Oxford Innovation, pursuant to which various patents we previously licensed from Oxford Innovation were assigned to us. We have ongoing obligations under the assignment agreement to make payments to Oxford Innovation until the patents expire and to continue to extend license rights to Oxford University, its employees, students, agents and appointees to use the technology for academic and research purposes. Our rights under the patents are subject to various grants of license rights, including (i) a license back to Oxford Innovation to maintain a pre-existing license for research use only, (ii) a pre-existing grant to a third party of non-exclusive rights under the patents covering a field of two infectious diseases, and (iii) a pre-existing grant to a third party of non-exclusive rights under the patents limited to the licensee's internal use to monitor vaccine response.

The amount we pay to Oxford Innovation for our royalty obligation is equal to a royalty rate in the low single digits. Our aggregate royalty obligation payments to Oxford Innovation through December 31, 2018 have been $3.1 million. Our royalty obligations to Oxford Innovation will cease when there are no valid patent claims still in force.

Our license agreement with Rutgers, The State University of New Jersey, or Rutgers, grants us an exclusive license to certain patents to manufacture and commercialize kits for *in vitro* diagnostic assays relating to TB other than in the ELISA format. The license was made in 2006 and has been amended in 2009, 2011, 2012, 2013, 2016 and 2017. Our license is royalty-bearing, worldwide, with the right to sublicense. We have not granted any sublicenses under this license. Rutgers has reserved the right to grant one additional license to this technology, limited to an ELISA format. To date, we do not believe Rutgers has entered into any such license.

We must make semi-annual royalty payments to Rutgers. Although the agreement contains minimum royalty obligations, the amount of royalties due based on our actual sales utilizing the licensed patents has exceeded the minimum for a number of years and we expect our royalties on actual sales will continue to exceed the minimum for the duration of our royalty obligations. We pay a royalty rate in the low single digits. Our aggregate payments to Rutgers through December 31, 2018 for signing fees, annual fees, milestones and royalties, including minimum royalties, have been $3.5 million. Our royalty obligations to Rutgers will cease when there are no valid patent claims still in force covering licensed products or assays. Previously, we made a number of other payments to Rutgers for license issue fees, annual license fees and milestone payments. No such future payments are required under the license.

Other

Our C6 Lyme ELISA kit incorporates the VIsE protein and C6 peptide, the most immunodominant portion of the VIsE protein. The protein is the subject of a patent held by Tulane University, or Tulane. We have also licensed four patents that relate to our C6 Lyme ELISA kit. The license from Tulane grants us the exclusive right to use the C6 peptide in a diagnostic test for Lyme disease in humans. The license from Tulane has a royalty rate in the single digits and expires in 2019 in the U.S. and in 2020 in other jurisdictions.

Trademarks and other protection

The trademarks we employ in our business include T-SPOT, T-Cell *Xtend*, T-Cell Select, Oxford Diagnostic Laboratories, or ODL, the Oxford Immunotec logo, our laboratory logo and the word Immunetics. We have obtained registrations in the United States for T-SPOT, T-Cell *Xtend*, Oxford Diagnostic Laboratories, the Oxford Immunotec logo and the word Immunetics. We have also obtained or are seeking registrations for certain of these trademarks in other jurisdictions, including the United Kingdom, the European Community, Japan and China. We have also secured numerous internet domain name registrations.

We have a policy of requiring all our employees to sign agreements that obligate them to maintain in confidence all confidential information they receive during the course of their employment, except in certain circumstances. Substantially all of our employees are also bound by invention assignment obligations, which provide that rights to all inventions and other types of intellectual property, whether or not patentable, conceived by them during the course of employment are assigned to us. We seek to enter into similar confidentiality and invention assignment agreements with our consultants.

Our trade secrets

There are several areas in which we have developed trade secrets relating to manufacturing that we believe provide a competitive advantage with respect to our T-SPOT.*TB* test. It is essential to the performance of ELISPOT tests used to detect the release of interferon-gamma from stimulated T cells that the microtiter plates used in the test be smoothly coated with the proper amount of interferon-gamma antibodies. For volume manufacturing, these coated plates must also meet stringent shelf life requirements. Our plate-coating process meets these criteria and cost-effectively provides reliable results. We believe this approach results in significant cost savings for us without sacrificing our compliance with either good manufacturing practices or our own high standards.

As part of our test offerings, we use unique formulations of peptides and other reagents that we believe are important to the accuracy of our tests. Further, we have devoted substantial time and resources to the development of processes and techniques that have resulted in cost reductions in our test manufacture and in assay performance in our service laboratory. In our U.K. ODL facility, we have streamlined the workflow process to allow for rapid throughput, which reduces labor costs and reduces the time we take to provide test results to our customers. In addition, we have developed and validated automated solutions for the assay process, including proprietary protocols for maximizing efficiencies garnered from the automation equipment. These methods are useful in our current test offerings, and will

be applicable to future tests we may develop using our T-SPOT technology and other platforms. We believe the manufacturing process and assay performance efficiencies we have developed and employ could not easily or quickly be developed by others.

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Manufacturing and laboratory facilities

Our tests are generally manufactured by us from materials we obtain from a limited number of suppliers. We manufacture our T-SPOT.*TB* test at our U.K. corporate headquarters in Abingdon, England, where we currently lease approximately 2,800 square feet of manufacturing space. The lease covering this space expires in 2020 and our current rent for the manufacturing space is $95,000 annually, which is subject to change. Our manufacturing facility is certified to ISO 13485. Our space in Abingdon also includes 6,400 square feet of storage/warehouse space. The leases covering this space expires in 2025 and our current rent for the storage/warehouse space is $67,000 annually, which is subject to change.

In June 2018, the Company entered into a lease for a new space in Abingdon, England, which extends through June 30, 2033, or the 143 Park Lease, that will allow us to combine our manufacturing, laboratory, storage and office operations into a single facility. The 143 Park Lease covers 27,000 square feet of laboratory, office, storage, manufacturing and other mixed use space. Initial rent under the 143 Park Lease is approximately $39,000 per month. When the lease on the Company's existing manufacturing and laboratory facility expires in December 2020, or possibly sooner, and we fully occupy the space subject to the 143 Park Lease, rent will increase to $79,000 per month. Rent will be reviewed for possible increases on June 1, 2021 and every third anniversary after that date. Select functional groups moved into the facility in the second half of 2018.

In connection with the sale of our U.S. Laboratory Services Business to Quest, we entered into a sublease with Quest for approximately 9,000 square feet of warehousing and office space in Norwood, MA. The sublease expires in November 2020. The base rent for the space subject to sublease is approximately $17,000 per month.

Key supplier relationships

We use a broad range of materials in the manufacture and performance of our diagnostic tests. We purchase all raw materials used in our tests from external suppliers. We purchase some materials from single sources for reasons of quality assurance, sole source availability, cost effectiveness or constraints resulting from regulatory requirements. We work closely with our suppliers to assure continuity of supply while maintaining high quality and reliability. To date, we have not experienced any significant difficulty in locating and obtaining the materials necessary to fulfill our production schedules. Because we believe that the only material supply relationships we have are those that pertain to our T-SPOT.*TB* test, we summarize these relationships below.

Mabtech AB. We entered into a purchase agreement with Mabtech AB, or Mabtech, in 2010, which was amended in 2013 and again in 2017. Pursuant to this agreement, Mabtech supplies the antibodies used to coat the membrane plates and for the detection procedure in our tests. We provide rolling forecasts of our anticipated purchases and portions of

those forecasts become binding orders. We receive pricing discounts based on the volume of our purchases. We have agreed to purchase these antibodies exclusively from Mabtech, although our exclusivity obligations may cease in the event Mabtech raises prices by more than a certain percentage over a defined period of time and declines to match a competitive third-party quotation for the antibodies.

The purchase agreement expires, unless earlier terminated, on December 31, 2023. Either party may terminate by providing written notice to the other in the event of a material uncured breach by the other party, a liquidation, insolvency, or bankruptcy proceeding involving the other party or cessation in trading by the other party.

EMD Millipore Corporation. We entered into a supply agreement with EMD Millipore Corporation, or Millipore, in 2009, which was amended in 2013 and 2014, and expired on December 31, 2018. In January 2019, we entered into a new agreement with Millipore (UK) Ltd, or Merck, a subsidiary of Millipore. Pursuant to the agreement, Merck supplies us with the membrane plates used in tests incorporating our T-SPOT technology. We provide rolling forecasts of our anticipated purchases and portions of those forecasts become binding orders. We receive pricing discounts based on the size of our orders. The agreement expires, unless earlier terminated, on December 31, 2024. Each party has the right to terminate in the event of a material uncured default by the other party. Each party also has the right to terminate the Agreement upon at least twelve months' prior written notice. In the event Merck exercises its right of termination, we may continue to purchase goods under the agreement for up to twelve months following termination.

MicroCoat Biotechnologie GmbH. Pursuant to our 2010 supply agreement with MicroCoat Biotechnologie GmbH, or MicroCoat, which was amended in 2016, MicroCoat performs antibody coating on membrane plates using plates and antibodies we supply. Under the supply agreement, we provide rolling forecasts of our anticipated purchases and portions of those forecasts become binding orders. We receive pricing discounts based on the size of our orders. These antibody-coated plates are a component of tests using our T-SPOT technology.

The current term of the agreement expires, unless earlier terminated, on December 31, 2019, subject to automatic renewals for additional one-year periods in the absence of specified notice by either party. Each party has the right to terminate in the event of a material uncured breach by the other party, or in the event of a bankruptcy or insolvency proceeding involving the other party.

StemCell Technologies, Inc. We entered into a supply agreement with StemCell Technologies, Inc., or StemCell, in 2008, which was amended in 2011 and again in 2017. Pursuant to this agreement, StemCell supplies us with a product that can be used with tests using our T-SPOT technology.

We have the exclusive right to market this product for use in association with ELISPOT tests to detect and/or quantify T-cells for use in the *in vitro* diagnosis, prognosis and/or clinical monitoring of infectious diseases, including tuberculosis, and non-infectious diseases and medical conditions, except our rights in China and India are non-exclusive. StemCell retains the right to sell this product for use in other applications and in our non-exclusive

territories. We are obligated to use commercially reasonable efforts to promote sales of the product for the applications to which we have exclusive rights.

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We paid a signing fee in the amount of $0.1 million and milestone payments in the aggregate amount of $0.2 million. We are not obligated to make additional milestone payments. We are obligated to pay an annual exclusivity fee during the term of the agreement, creditable against certain future purchases. Our product purchases exceeded the amount of the exclusivity fee in 2017. We receive pricing discounts based on our quarterly orders. We have also agreed to make StemCell our supplier of choice for certain types of products, subject to performance obligations of StemCell, and we are generally obligated to acquire all of our requirements for such products from StemCell.

The agreement expires, unless earlier terminated, on December 31, 2023, but will continue indefinitely thereafter in the absence of specified notice by either party. Each party may terminate for material uncured breach, the insolvency or bankruptcy of the other party or the cessation of trading by or dissolution of the other party.

Life Technologies Corporation. We entered into a supply and reseller agreement with Life Technologies Corporation, or Life Tech, in 2013, amended in 2014, 2016 and 2017, which expired on December 31, 2018. In January 2019, we entered into an amended and restated supply and reseller agreement with Life Tech, which will expire on December 31, 2019. Pursuant to the Agreement we purchase and resell a product that can be used in performing assays using our T-SPOT technology. We have a minimum annual purchase obligation under the agreement, as well as obligations to purchase certain amounts based on our rolling forecasts of anticipated purchases. Either party may terminate for a material uncured breach, the insolvency or bankruptcy of the other party, if one of our twelve-month forecasts does not reflect any anticipated purchases of product or if we purchase no product during a consecutive twelve-month period.

Key customer relationships

Our customers include independent laboratories, large hospital systems and public and private institutions. Our customer relationships also include our distributors outside of the U.S. We believe our relationships with Quest and with two of our distributors are key customer relationships.

Quest Diagnostics, Incorporated. We have a supply agreement with Quest Diagnostics, Incorporated, or Quest, which was made as of the closing of the sale of our U.S. Laboratory service business to Quest. Pursuant to the supply agreement, we sell T-SPOT.*TB* kits and certain accessories to Quest. The agreement expires on November 6, 2025. Each party may terminate the supply agreement for a material uncured breach or in any event of bankruptcy or an equivalent winding up of the other party’s business.

Shanghai Fosun Long March Medical Science Co. Ltd. We have a distribution agreement with Shanghai Fosun Long March Medical Science Co. Ltd., or Fosun, pursuant to which Fosun distributes our TB-related products in China. Under the distribution agreement, Fosun serves as our exclusive distributor in a territory consisting of the People’s

Republic of China, including Macau Special Administrative Regions, and also serves as our non-exclusive distributor in Hong Kong. Fosun commits to using its best efforts to promote, sell and distribute our products in the territory in compliance with our policies and procedures and applicable law. The agreement imposes certain annual minimum purchase obligations at agreed upon pricing and covers our products, as well as other accessories which may be used in conjunction with our products. Fosun is obligated to refrain from dealing in any products in the territory which would be competitive with ours through a period extending 12 months after the termination of the agreement.

The agreement expires on January 1, 2021. Either party may terminate the agreement for a material uncured breach or in the event of bankruptcy or an equivalent winding up of the other party's business. We may terminate the agreement if Fosun does not meet the minimum purchase requirements, for late payment or if Fosun undergoes a change in control. We amended the agreement twice during 2018 to adjust the rebate available upon Fosun's achievement of minimum purchase quantities.

Riken Genesis Co., Ltd. We sell our T-SPOT.*TB* test to a Japanese importer, Riken Genesis Co., Ltd., or Riken, which also serves as our marketing authorization holder in Japan, a position required by Japanese regulatory authorities. We entered into a marketing authorization holder agreement with Riken in 2011 and it was amended in 2013, 2016 and 2017. Pursuant to this agreement, Riken provides services for importation into Japan. We initially paid an initiation fee to Riken in the amount of ¥200,000, or approximately $1,600. We currently pay Riken a flat monthly fee in the amount of ¥150,000, or approximately $1,300, and also pay a single-digit percentage commission based on the prices at which end users purchase our products. The initial agreement with Riken had a one-year term and automatically renews for additional one-year periods in the absence of specified notice by either party. Either party may terminate for a material uncured breach or in the event of bankruptcy, insolvency or similar proceedings of the other party.

Government regulation

Federal Food, Drug, and Cosmetic Act

In the United States, *in vitro* diagnostics, or IVDs, are regulated by the FDA as either medical devices or biological products under the Federal Food, Drug, and Cosmetic Act, or FDCA, depending on their intended use. IVDs that are used as diagnostics are regulated as medical devices.

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Marketing pathways

There are two regulatory pathways to receive authorization to market IVDs intended for diagnostic purposes: a premarket application, or PMA, and a 510(k) premarket notification. The FDCA establishes a risk-based standard for determination of the pathway for which a particular IVD device is eligible.

The information that must be submitted to the FDA to obtain clearance or approval to market a new medical device varies depending on how the medical device is classified by the FDA. Medical devices are classified into one of three classes on the basis of the controls necessary to reasonably ensure their safety and effectiveness. Class I devices are subject to general controls, including labeling and adherence to the FDA's quality system regulation, which establishes device-specific good manufacturing practices. Class II devices are subject to general controls and special controls, including performance standards and post-market surveillance. Class III devices are subject to these requirements as well as to premarket approval. Most Class I devices are exempt from premarket submissions to the FDA; most Class II devices require the submission of a 510(k) premarket notification to the FDA; and Class III devices require submission of a PMA application. Our T-SPOT.*TB* test is a Class III device and our C6 Lyme ELISA kit is a Class II device. We have other Class II devices that have received 510(k) clearance from FDA that we acquired through our acquisition of Immunetics.

Premarket approval. The PMA process, by which we received marketing authorization for our T-SPOT.*TB* test in 2008, is complex, costly and time consuming. A PMA application must be supported by detailed and comprehensive scientific evidence, including clinical data, to demonstrate the safety and efficacy of the medical device for its intended purpose. If the device is determined to present a "significant risk," the sponsor may not begin a clinical trial until it submits an investigational device exemption, or IDE, to the FDA and obtains approval from the FDA to begin the trial. After the PMA application is submitted, the FDA has 45 days to make a threshold determination that the application is sufficiently complete to permit a substantive review. If the application is complete, the FDA will accept it for filing. The FDA is subject to a non-binding performance goal review time for a PMA application of 180 days from the date of filing, although in practice this review time is often longer. Questions from the FDA, requests for additional data and referrals to advisory committees may delay the process considerably. Indeed, the total process may take several years and there is no guarantee that the PMA application will ever be approved. Even if approved, the FDA may limit the indications for which the device may be marketed. The FDA may also request additional clinical data as a condition of approval or after the PMA is issued. Any changes to the medical device may require a supplemental PMA application to be submitted and approved. Since we received initial PMA application approval of our T-SPOT.*TB* test in 2008, the FDA has granted approval for ten supplemental PMA applications for our T-SPOT.*TB* test, including supplements relating to the use of our T-Cell *Xtend* reagent with our T-SPOT.*TB* test.

510(k) Clearance. Our C6 Lyme ELISA kit has obtained 510(k) clearance from FDA. A traditional 510(k) submission requires demonstration of substantial equivalence to a previous legally marketed device that was not subject to PMA. If a substantial equivalence cannot be demonstrated and the test is of low to moderate risk, the FDA may allow a *de novo* 510(k) submission. Submission of either a traditional or *de novo* 510(k) notification is subject to a 90-day FDA review period. Questions from the FDA, requests for additional data and referrals to advisory committees may delay

the process considerably and the FDA may ultimately limit the indications for which the device may be marketed. Marketing of an IVD medical device may begin as soon as FDA clearance is granted.

Post-marketing regulations and controls

Under the medical device regulations, the FDA regulates quality control and manufacturing procedures by requiring us to demonstrate and maintain compliance with the quality system regulation, which sets forth the FDA's current good manufacturing practices requirements for medical devices. The FDA monitors compliance with the quality system regulation and current good manufacturing practices requirements by conducting periodic inspections of manufacturing facilities. FDA inspections in the United States are typically unannounced. FDA inspections outside the United States are coordinated with the companies being inspected. Violations of applicable regulations noted by the FDA during inspections of our manufacturing facilities could adversely affect the continued marketing of our tests.

The FDA also enforces post-marketing controls that include the requirement to submit product reports to the agency when a manufacturer becomes aware of information suggesting that any of its marketed products may have caused or contributed to a death, serious injury or serious illness or any of its products has malfunctioned and that a recurrence of a malfunction would likely cause or contribute to a death or serious injury or illness. The FDA relies on product reports to identify product problems and utilizes these reports to determine, among other things, whether it should exercise its enforcement powers. The FDA also enforces the requirement that manufacturers submit reports of recalls and field actions to the FDA if the actions are initiated 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 may also require post-market surveillance studies for specified devices.

FDA regulations also govern, among other things, the preclinical and clinical testing, manufacture, distribution, labeling and promotion of medical devices and biological products. In addition to compliance with good manufacturing practices and product reporting requirements, we are required to comply with the FDCA's general controls, including establishment registration, device listing and labeling requirements. If we fail to comply with any requirements under the FDCA, we could be subject to, among other things, fines, injunctions, civil penalties, recalls or product corrections, total or partial suspension of production, denial of premarket notification clearance or approval of products, rescission or withdrawal of clearances and approvals, and criminal prosecution. We cannot assure you that any final FDA policy, once issued, or future laws and regulations concerning the manufacture or marketing of medical devices will not increase the cost and time to market of new or existing tests. If we fail to comply with these FDA regulations or guidelines, we may be subject to warnings from, or enforcement action by, the FDA.

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International Medical Device Regulations

International marketing of medical devices is subject to foreign government regulations, which vary substantially from country to country. The European Commission is the legislative body responsible for directives with which manufacturers selling medical products in the European Union and the European Economic Area, or EEA, must comply. The European Union includes most of the major countries in Europe, while other countries, such as Switzerland, are part of the EEA and have voluntarily adopted laws and regulations that mirror those of the European Union with respect to medical devices. The European Union has adopted directives that address regulation of the design, manufacture, labeling, clinical studies and post-market vigilance for medical devices, including IVDs. Devices that comply with the requirements of a relevant directive, including the IVD Directive (Directive 98/79 EC), will be entitled to bear the CE conformity marking, indicating that the device conforms to the essential requirements of the applicable directives and, accordingly, can be marketed throughout the European Union and EEA.

Outside of the European Union, regulatory pathways for the marketing of medical devices vary greatly from country to country. In many countries, local regulatory agencies conduct an independent review of IVD medical devices prior to granting marketing approval. For example, in China, approval by the CFDA, must be obtained prior to marketing an IVD medical device. In Japan, approval by the MHLW following review by the Pharmaceuticals and Medical Devices Agency, or the PMDA is required prior to marketing an IVD. The process in such countries may be lengthy and require the expenditure of significant resources, including the conduct of clinical trials. In other countries, the regulatory pathway may be shorter and/or less costly. The timeline for the introduction of new IVD medical devices is heavily impacted by these various regulations on a country-by-country basis, which may become more lengthy and costly over time.

Our T-SPOT.*TB* test has been approved for sale in over 50 countries, including in Europe, China, and Japan. Our T-SPOT.*TB* test obtained a CE mark in 2004, CFDA approval in China in 2010 and re-registration in 2014, and MHLW approval in Japan in 2012. Our T-SPOT.*CMV* test obtained a CE mark in 2015 and our C6 Lyme ELISA kit obtained a CE mark in 2011.

Laboratory certification, accreditation and licensing

Our laboratory located in the United Kingdom operates under accreditation by the United Kingdom Accreditation Service, or UKAS, for the International Standard: ISO 17025:2017 (General requirements for the competence of testing and calibration laboratories). Compliance with this standard is required to maintain accreditation and the continued use of the UKAS logo on our laboratory documentation. National Health Service (NHS)-based customers require that the testing services they procure operate to an accredited quality management system, which is evidenced by the UKAS accreditation. Therefore, a failure to maintain this accreditation could cause us to lose a substantial majority of our U.K. service business.

HIPAA and other privacy laws

U.S. Health Insurance Portability and Accountability Act, or HIPAA, established for the first time in the United States comprehensive protection for the privacy and security of health information. The HIPAA standards apply to three types of organizations, or Covered Entities: health plans, healthcare clearing houses, and healthcare providers that conduct certain healthcare transactions electronically. Covered Entities and their Business Associates, as defined in HIPAA, must have in place administrative, physical, and technical standards to guard against the misuse of individually identifiable health information. Since the divestiture of our U.S. Laboratory Services Business, we are no longer a Covered Entity. We may conduct other activities that may implicate HIPAA, such as conducting clinical studies or entering into specific kinds of relationships with a Covered Entity or a Business Associate of a Covered Entity.

If we or our operations are found to be in violation of HIPAA, HITECH or their implementing regulations, we may be subject to penalties, including civil and criminal penalties, fines, and exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. HITECH increased the civil and criminal penalties that may be imposed against Covered Entities, their Business Associates and possibly other persons, 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 attorney's fees and costs associated with pursuing federal civil actions.

Our activities must also comply with international privacy laws that impose restrictions on the access, use, and disclosure of health information. For example, the European General Data Protection Regulation covers personal information of citizens of the European Union and imposes strict penalties for noncompliance. All of these laws may impact our business. Our failure to comply with these privacy laws or significant changes in the laws could significantly impact our business and our future plans.

U.S. federal and state "anti-kickback" restrictions

The federal Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under a federal healthcare program, such as the Medicare and Medicaid programs. The term "remuneration" is not defined in the federal Anti-Kickback Statute and has been broadly interpreted to include anything of value, including for example, gifts, discounts, the furnishing of supplies or equipment, credit arrangements, payments of cash, waivers of payment, ownership interests and providing anything at less than its fair market value.

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Many states have also adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs, and do not contain identical safe harbors.

If we or our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participation in U.S. federal or state health care programs, and the curtailment or restructuring of our operations. We may also be subject to similar foreign laws and regulations.

U.S. health care reform

In March 2010, the PPACA was enacted, which included measures that significantly changed the way healthcare is financed by both governmental and private insurers. Changes were made to the PPACA as part of the Tax Cuts and Jobs Act of 2017 to remove certain parts of the original legislation and the current Congress continues to make efforts to repeal and/or replace the PPACA. The Physician Payment Sunshine Act, enacted as part of PPACA, has not been repealed and requires medical device manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any “transfer of value” made or distributed to such entities, as well as any investment interests held by physicians and their immediate family members. Manufacturers are required to report this information to CMS. Various states have also implemented regulations prohibiting certain financial interactions with healthcare professionals and/or mandating public disclosure of such financial interactions. We may incur significant costs to comply with such laws and regulations now or in the future.

Other laws

We are also subject to numerous U.S. federal, state and local laws as well as international laws relating to such matters as safe working conditions, manufacturing practices, environmental protection, fire hazard control, and transportation and disposal of blood and hazardous or potentially hazardous substances. We may incur significant costs to comply with such laws and regulations now or in the future.

Employees

As of December 31, 2018, we had 210 employees. None of our employees is covered under a collective bargaining agreement. We have not experienced any work stoppages and we believe our employee relations are good.

Environmental matters

Our operations require the use of hazardous materials, which, among other matters, subjects us to a variety of national, state and local environmental, health and safety laws, regulations and permitting requirements, including those relating to the handling, storage, transportation and disposal of biological and hazardous materials and wastes. The primary hazardous materials we handle or use include human blood samples and solvents. Some of the regulations under the current regulatory structure provide for strict liability, holding a party liable for contamination at currently and formerly owned, leased and operated sites and at third-party sites without regard to fault or negligence. We could be held liable for damages and fines as a result of our, or others', operations or activities should contamination of the environment or individual exposure to hazardous substances occur. We could also be subject to significant fines for failure to comply with applicable environmental, health and safety requirements. We cannot predict how changes in laws or development of new regulations will affect our business operations or the cost of compliance.

Available information

Access to our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to these reports filed with or furnished to the SEC may be obtained through the investor section of our website at *www.oxfordimmunotec.com* as soon as reasonably practical after we electronically file or furnish these reports. We do not charge for access to and viewing of these reports. Information in the investor section and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein by reference. In addition, the public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. Also, our filings with the SEC may be accessed through the SEC's website at *www.sec.gov.* All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law.

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Corporate information

Oxford Immunotec Global PLC was incorporated in England and Wales in 2013. Our principal executive offices are located at 94C Innovation Drive, Milton Park, Abingdon, OX14 4RZ, United Kingdom, and our telephone number is +44 (0) 1235 442 780. Our internet website is www.oxfordimmunotec.com. The information on, or that can be accessed through, our website is not part of this Annual Report on Form 10-K.

Item 1A. Risk Factors

Risks related to our business.

We have a history of losses and we cannot be certain that we will achieve or sustain profitability.

We have a history of losses and may continue to incur losses from continuing operations. For the fiscal years ended December 31, 2018, 2017 and 2016, we had income (losses) from continuing operations of $12.5 million, $(33.2) million and $(21.6) million, respectively, and we had an accumulated deficit at December 31, 2018 of $80.8 million. Substantially all of our operating losses in these periods resulted from costs incurred in connection with sales and marketing of our T-SPOT.*TB* test, general and administrative costs associated with our operations and our research and development programs. We anticipate that our operating losses may decline following the sale of our U.S. Laboratory Services Business to Quest, as we intend to reduce overhead costs and refocus our business on the sale of kits. Because of the numerous risks and uncertainties associated with developing and commercializing diagnostic products, we cannot be certain that we will achieve or sustain profitability. Our ability to generate profits on sales of our T-SPOT.*TB* test is subject to market acceptance in market segments we currently serve, as well as in new market segments and new geographies, and our ability to obtain regulatory body clearance to market any of our products. In addition, we may be compelled to sell our T-SPOT.*TB* test at lower prices if, for example, our customers or prospective customers are unwilling to pay for our tests at current pricing levels or as a result of increased competition generally. Any price erosion would impede our ability to generate revenue. If we are unable to generate sufficient revenue, we will not become profitable and may be unable to continue operations without continued funding.

We may require substantial additional capital resources to fund our operations. We may not be able to obtain additional capital resources on favorable terms and if we cannot find additional capital resources, we may have difficulty operating our business. Raising additional capital may also cause dilution to our existing shareholders.

As of December 31, 2018, we had cash and cash equivalents of $192.8 million and working capital (total current assets less total current liabilities) of $198.8 million. While we anticipate that our current cash, cash equivalents and cash generated from operations will be sufficient to meet our projected operating plans for at least the next 12 months, we may require additional funds, either through additional equity or debt financings, strategic collaboration agreements, sale of assets or from other sources. Additional financing opportunities may not be available to us, or if available, may not be on favorable terms. Further, 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 may include liquidation or other preferences that adversely affect the rights of our shareholders. Our future capital requirements will depend on many factors, including revenue generated from the sale of our T-SPOT.*TB* test, margins, operating expenses and our ability to control costs associated with our operations, and the costs of filing, prosecuting, maintaining, defending and enforcing any patent claims and other intellectual property rights. The availability of additional capital will also depend on many factors, including the market price of our ordinary shares and the availability and cost of additional equity capital from existing and potential new investors, our ability to retain the listing of our ordinary shares on The NASDAQ Global Market and general economic and industry conditions affecting the availability and cost of capital.

Debt 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 additional funds through collaboration, strategic alliance and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates beyond the rights we have already relinquished, or grant licenses on terms that are not favorable to us.

We are currently heavily dependent on the successful further commercialization of our T-SPOT.TB test and, if we encounter delays or difficulties in the further commercialization of this product, our business could be harmed.

Our future success is heavily dependent upon the successful further commercialization of our T-SPOT.*TB* test. Following the completion of the sale of our U.S. laboratory services business to Quest in November 2018, we expect substantially all of our revenue to be derived from sales of products such as diagnostic test kits and related accessories going forward. There is no assurance that we will continue to generate revenues from our T-SPOT.*TB* test, or any products under development, in the future. Our business could be materially harmed if we encounter difficulties in the further commercialization of this product, including, among others: failure to achieve sufficient market acceptance by hospitals and public health departments as well as physicians, third-party payors and others in the medical community; the inability to compete with other diagnostic methods, including the TST; the inability to maintain and expand our sales, marketing and distribution networks; the inability to manage anticipated growth; the inability to obtain and/or maintain necessary regulatory approvals; and the inability to effectively protect our intellectual property.

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If we do not achieve, sustain or successfully manage our anticipated growth, our business and financial results may be adversely affected.

Further development and commercialization of our T-SPOT.*TB* test and other diagnostic product candidates will require us to expand our sales, marketing and distribution networks. Such growth may place significant strains on our management and our internal systems and processes, as well as potentially those of our suppliers, and if we cannot effectively manage expanding operations and costs, we may not be able to continue to grow or we may grow at a slower pace and our business and financial results could be adversely affected.

Our financial results will depend on the market acceptance and increased demand of our products by hospitals and public health departments, as well as physicians and others in the medical community.

Our future success depends on our products gaining sufficient market acceptance by hospitals and public health departments. If our products do not achieve an adequate level of acceptance by such customer groups, we may not generate enough revenue to become profitable. For example, the degree of market acceptance of our T-SPOT.*TB* product will depend on a number of factors, including:

- clinical guidelines relative to the screening for, and diagnosis and monitoring of, TB infection;
- the efficacy and potential advantages of our T-SPOT.*TB* test over alternative tests;
- the willingness of our target customers to accept and adopt our T-SPOT.*TB* test;
- the ability to offer attractive pricing for our T-SPOT.*TB* test;
- the strength of marketing and distribution support and the timing of market introduction of competitive products; and
- outcomes from clinical studies and other publicity concerning our T-SPOT.*TB* test or competing products.

Our efforts to educate physicians and other members of the medical community on the benefits of our T-SPOT.*TB* test may require significant resources and may never be successful. Such efforts to educate the marketplace may require more resources than are required by conventional technologies marketed by our competitors. In particular, continuing to gain market acceptance for our T-SPOT.*TB* test in nascent markets could be challenging. In certain markets, including, for example, Japan and China, our potential for future growth is difficult to forecast. If we were to incorrectly forecast our ability to penetrate these markets, expenditures that we make may not result in the benefits that we expect, which could harm our results of operations. Moreover, in the event that our T-SPOT.*TB* test is the subject of guidelines, clinical studies or scientific publications that are unhelpful or damaging, or otherwise call into question the benefits of our T-SPOT.*TB* test, we may have difficulty in convincing prospective customers to adopt our test. Moreover, the perception by the investment community or shareholders that recommendations, guidelines or studies will result in decreased use of our products could adversely affect the prevailing market price for our ordinary shares. Similar challenges apply to all of the products in our pipeline.

The success of our T-SPOT.TB test depends on the continued demand for diagnostic products for tuberculosis.

Even if we achieve market acceptance, our success will depend on continued demand for diagnostic products for tuberculosis. Tuberculosis screening policies could change such that tests are conducted less frequently or in fewer instances. For example, healthcare institutions facing increased cost control requirements could determine to reduce employee testing. In addition, various institutions or governing bodies may decide that the incidence of TB has dropped sufficiently within their screening population so as to permit reduced testing (e.g., U.S. military guidelines were updated in recent years such that testing may now be required in fewer instances than under previous guidelines). Changes to immigration policies and policies relating to resettlement of refugees, as well as other policy changes may substantially reduce testing in the markets we serve and could have a material and adverse effect on our business.

New market opportunities may not develop as quickly as we expect, limiting our ability to market and sell our T-SPOT.TB test successfully.

We intend to take steps to continue to increase the presence of our T-SPOT.*TB* test in new markets both in the United States and internationally. We intend to expand our sales force globally and establish additional distributor relationships outside of our direct markets to better access international markets. We believe these opportunities will take substantial time to develop or mature, however, and we cannot be certain that these market opportunities will develop as we expect. The future growth and success of our T-SPOT.*TB* test in these markets depends on many factors beyond our control, including recognition and acceptance by the scientific community in that market and the prevalence and costs of competing methods of tuberculosis screening. If the markets for our T-SPOT.*TB* test do not develop as we expect, our business may be adversely affected.

In connection with the Transaction, we entered into a supply agreement and strategic collaboration agreement with Quest. If we are unable to meet our obligations under these agreements, our business could be adversely affected.

In connection with the Transaction, we entered into a supply agreement pursuant to which we agreed to sell, and Quest agreed to purchase, T-SPOT.*TB* test kits and related accessories. Additionally, we entered into a strategic collaboration agreement with Quest to drive continued growth of T.SPOT.*TB* testing in the U.S. If we fail to meet our obligations under the supply agreement or if our collaboration with Quest does not result in the continued growth of T.SPOT.*TB* testing in the U.S., our business may be adversely affected.

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Our T-SPOT.TB test competes with other diagnostic testing methods that may be more widely accepted than our test, and may compete with new diagnostic tests that may be developed by others in the future, which could impair our ability to maintain and grow our business and remain competitive.

The clinical diagnostics market is highly competitive, and we must be able to compete effectively against existing and future competitors in order to be successful. In selling our T-SPOT.*TB* test, we compete primarily with existing diagnostic technologies, particularly the TST, which is widely used as a test for TB infection. In addition, we compete with QFN which, like our T-SPOT.*TB* test, employs an IGRA method for detecting tuberculosis infection. If we are unable to differentiate our diagnostic tests from those of our competitors, our business may be materially and adversely affected. In addition, improvements in these technologies or the development of new technologies for diagnosing tuberculosis and the introduction of products that compete with our T-SPOT.*TB* test could adversely impact our ability to sell our T-SPOT.*TB* test or the sales price of the test. This could impact our ability to market our test and/or secure a distribution partner, both of which could have a substantial impact on the value of our T-SPOT.*TB* test.

We also face competition in the development, manufacture, marketing and commercialization of diagnostic products from a variety of other sources, such as academic institutions, government agencies, research institutions and other life sciences companies. These competitors are working to develop and market other diagnostic tests, systems, products and other methods of detecting, preventing or reducing tuberculosis.

Among the many experimental diagnostics being developed around the world, there may be diagnostics unknown to us that may compete with our T-SPOT.*TB* test. Many of our potential competitors have much greater capital resources, manufacturing, research and development resources and production facilities than we do. Competitors with greater resources may be able to offer tests and/or services at prices at which we are unable to compete and more quickly develop improvements than we are. Many of them may also have more experience than we have in preclinical testing and clinical trials of new diagnostic tests.

The markets for our T-SPOT.*TB* test are subject to changing technology, new product introductions and product enhancements, and evolving industry standards. The introduction or enhancement of products embodying new technology or the emergence of new industry standards could render existing products obsolete or result in short product life cycles or our inability to sell our T-SPOT.*TB* test without offering a significant discount.

Our future success depends on our ability to successfully develop, obtain clearance or approval for and commercialize new products.

Our future success partially depends on our ability to successfully develop and market new products. Our ability to develop any of these products is dependent on a number of factors, including funding availability to complete development efforts; our ability to develop products that adequately detect or measure the targeted function, condition or disease; our ability to secure required FDA or other regulatory clearance or approval and our ability to obtain licenses to necessary third-party intellectual property. We may encounter problems in the development phase for our products, which can result in substantial setbacks and delays or abandonment of further work on the potential product. There can be no assurance that we will not encounter such setbacks with the products in our pipeline, or that funding from outside sources and our revenue will be sufficient to bring any future product to the point of commercialization.

In addition, our future success partially depends on the successful completion of clinical trials demonstrating the utility of our product candidates. We currently have a number of pipeline products in development, some of which are or may become the subject of pivotal trials to demonstrate sufficient utility to support successful market adoption and/or to obtain regulatory approval for sale. Not all of our clinical trials may actually result in the successful commercialization of a product. We will not be able to commercialize our pipeline products if clinical trials do not produce successful results or if clinical trials do not demonstrate utility. In addition, the process for the completion of clinical trials and the regulatory approval submission process are lengthy and may be subject to a number of delays for various reasons, which could delay the commercialization of any product. If our development projects are not successful or are significantly delayed, we may not recover our substantial investments in the pipeline products, and our failure to bring these pipeline products to market on a timely basis, or at all, would adversely affect our business, results of operations and financial condition.

Even if we are successful in developing new products and securing regulatory approval to market them, we may not be able to achieve marketplace acceptance for our new products or generate significant revenue from their sale. As with our current T-SPOT.*TB* test, the success of any future products will depend upon the degree of market acceptance by physicians, hospitals, third-party payors and others in the medical community. Achieving market acceptance will require us to expend substantial time and resources to educate physicians and other members of the medical community on the benefits of any new product we develop and we may never be successful in gaining market acceptance of our new products. There can be no assurance that the products we seek to develop will work effectively in the marketplace, or that we will be able to produce them on an economical basis.

If we are unable to maintain and expand our network of direct sales representatives and independent distributors, we may not be able to generate anticipated sales.

We sell our T-SPOT.*TB* test through our own sales force in the United States, certain European countries and Japan and we sell through distributors in other parts of the world such as in China. Our operating results are directly dependent upon the sales and marketing efforts of not only our employees, but also our independent distributors. We expect our direct sales representatives and independent distributors to develop long-lasting relationships with the providers they serve. If our direct sales representatives or independent distributors fail to adequately promote, market and sell our product, our sales could significantly decrease.

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We face significant challenges and risks in managing our geographically dispersed sales and distribution network and retaining the individuals who make up that network. If a substantial number of our direct sales representatives were to leave us within a short period of time, or if a substantial number of our independent distributors were to cease to do business with us within a short period of time, our sales could be adversely affected. If any significant independent distributor were to cease to distribute our product, our sales could be adversely affected. In such a situation, we may need to seek alternative independent distributors or increase our reliance on our direct sales representatives, which may not prevent our sales from being adversely affected. If a direct sales representative or independent distributor were to depart and be retained by one of our competitors, we may be unable to prevent them from helping competitors solicit business from our existing customers, which could further adversely affect our sales. Because of the intense competition for their services, we may be unable to recruit additional qualified independent distributors or to hire additional qualified direct sales representatives to work with us. We may also not be able to enter into agreements with them on favorable or commercially reasonable terms, if at all. Failure to hire or retain qualified direct sales representatives or independent distributors would prevent us from expanding our business and generating sales. See "Certain of our customers account for a significant portion of our revenue."

As we launch new products and increase our sales, marketing and distribution efforts with respect to our T-SPOT.*TB* test, we will need to expand the reach of our sales, marketing and distribution networks. Our future success will depend largely on our ability to continue to hire, train, retain and motivate skilled direct sales representatives and independent distributors with significant technical knowledge in various areas. New hires require training and take time to achieve full productivity. If we fail to train new hires adequately, or if we experience high turnover in our sales force in the future, we cannot be certain that new hires will become as productive as may be necessary to maintain or increase our sales.

If we are unable to expand our sales and marketing capabilities domestically and internationally, we may not be able to effectively commercialize our products, which would adversely affect our business, results of operations and financial condition.

Health insurers and other payors may decide not to cover, or may discontinue reimbursing, our T-SPOT.TB test or any other diagnostic tests we offer or may offer, or may provide inadequate reimbursement, which could jeopardize our ability to expand our business.

Although for many of our current customers, the cost of screening their employees for tuberculosis is not reimbursable, our business is somewhat impacted, and in the future may be more greatly impacted, by the level of reimbursement from payors or governmental limitations on price. In the United States, the regulatory process allows diagnostic tests to be marketed regardless of any coverage determinations made by payors. For new diagnostic tests, each payor makes its own decision about which tests it will cover, how much it will pay and whether it will continue reimbursing the test. Clinicians may order diagnostic tests that are not reimbursed if the patient is willing to pay for the test without reimbursement, but coverage determinations and reimbursement levels and conditions are important to the commercial success of a diagnostic product. In addition, eligibility for coverage does not imply that any product will be covered and reimbursed in all cases or reimbursed at a rate that allows our potential customers to make a profit

or even cover their costs.

CMS establishes reimbursement payment levels and coverage rules for Medicare. CMS currently covers our T-SPOT.*TB* test. If CMS were to place significant restrictions on the use of our tests, reduce payment amounts or eliminate coverage altogether, our ability to generate revenue from our diagnostic tests could be limited. For example, payment for diagnostic tests furnished to Medicare beneficiaries is made based on a fee schedule set by CMS. In July 2013, CMS released certain proposals that re-examined payment amounts for tests reimbursed under the Medicare clinical laboratory fee schedule due to changes in technology. CMS also proposed to bundle the Medicare payments for certain laboratory tests ordered while a patient received services in a hospital outpatient setting, replacing the current methodology to make separate payments for the test. These changes went into effect on January 1, 2014. In addition, payment methodologies may be subject to changes in healthcare legislation. In February 2012, President Obama signed the Middle Class Tax Relief and Job Creation Act of 2012, which mandated an additional change in reimbursement for clinical laboratory services payments. This legislation required CMS to reduce the Medicare clinical laboratory fee schedule by 2% in 2013, which in turn serves as the base for 2014 and subsequent years. Levels of reimbursement may continue to decrease in the future, and future legislation, regulation or reimbursement policies of third-party payors may harm the demand and reimbursement available for our T-SPOT.*TB* test, which in turn, could harm our product pricing and sales. If our customers are not adequately reimbursed for our T-SPOT.*TB* test, they may reduce or discontinue purchases of our product, which would cause our revenues to decline.

The Protecting Access to Medicare Act of 2014, or PAMA, includes extensive revisions to the Medicare payment, coding, and coverage requirements for clinical diagnostic laboratory tests as well as creates a new subcategory of Clinical Diagnostic Lab Test (CDLT) called Advanced Diagnostic Laboratory Tests (ADLTs) with separate reporting and payment requirements. Beginning in 2018, the Medicare payment rate for each CDLT is equal to the weighted median amount for the test from the most recent data collection period. The payment rate will apply to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. The PAMA rate changes to our tests that were impacted did not materially affect our payments beginning in 2018; however, we cannot predict how this may change future payment in coming years. Per the final payment rates and supporting documentation for the new private payor rate-based CLFS payment system published by CMS in late 2017, CMS reimbursement per test for CPT code 86481 is expected to be $100 in years 2018, 2019, and 2020.

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In addition, state Medicaid plans and private commercial payors establish rates and coverage rules independently. As a result, the coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our tests to each payor separately, with no assurance that coverage or adequate reimbursement will be obtained. Even if one or more third-party payors decides to reimburse for our tests, that payor may reduce utilization or stop or lower payment at any time, which could reduce our revenue. We cannot predict whether or when third-party payors will cover our tests or offer adequate reimbursement to make them commercially attractive. Clinicians may decide not to order our tests if inadequate third-party payments result in additional costs to the patient.

We are also subject to foreign reimbursement and payment schemes in the international markets we serve, including Japan, Switzerland, Germany, France and South Korea. Decisions by health insurers or other third-party payors in these markets not to cover, or to discontinue reimbursement, or governmental limitations on price could materially and adversely affect our business.

Billing complexities associated with obtaining payment or reimbursement for our tests may negatively affect our revenue, cash flow and profitability.

Although third-party payors only accounted for a small percentage of our total revenue for the year ended December 31, 2018, we currently rely in part, and may in the future more heavily rely, on obtaining third-party payment or reimbursement for our test. Our customers receive payment from individual patients and from a variety of payors, such as commercial insurance carriers, including managed care organizations and governmental programs, primarily Medicare and Medicaid in the United States. Each payor typically has different billing requirements, and the billing requirements of many payors have become increasingly stringent.

Among the factors complicating billing of, and obtaining payment through, third-party payors are:

- disputes among payors as to which party is responsible for payment;
- disparity in coverage among various payors;
- disparity in information and billing requirements among payors;
- incorrect or missing billing information, which is required to be provided by the ordering physician; and
- payments may be sent directly to patients rather than to us.

These billing complexities, and the related uncertainty in obtaining payment for our tests, could negatively affect our customers' ability to get paid for our test and, by extension, our revenue, cash flow and profitability.

We depend upon a limited number of suppliers, and certain components of our products may only be available from a sole source or limited number of suppliers.

Our tests are generally assembled by us from supplies we obtain from a limited number of suppliers. Critical components required to assemble our tests may only be available from a sole or limited number of component suppliers. For example, we source key components of our T-SPOT.*TB* test from EMD Millipore Corporation, Stemcell Technologies Inc., Mabtech AB, MicroCoat Biotechnologie GmbH and Life Technologies Corporation, any of whom would be difficult to replace. Even if the key components that we source are available from other parties, the time and effort involved in obtaining any necessary regulatory approvals for substitutes could impede our ability to replace such components timely or at all. The loss of a sole or key supplier would impair our ability to deliver products to our customers in a timely manner and would adversely affect our sales and operating results and negatively impact our reputation. Our business would also be harmed if any of our suppliers could not meet our quality and performance specifications and quantity and delivery requirements.

Certain of our customers account for a significant portion of our revenue.

We sell our T-SPOT.*TB* test through a direct sales force in the United States, certain European countries and Japan. In Japan, while we maintain end-user relationships through our direct sales force, we sell through a single importer of record, Riken. In other parts of the world, we sell through distributors. For example, in China, we sell through a single distributor, Fosun. For the year ended December 31, 2018, sales to Fosun and through Riken together accounted for 46% of our total revenue, with Fosun accounting for 27% and Riken accounting for 19%. As a result of the Transaction, Quest has become a significant customer in the U.S. and will comprise a significant portion of our U.S. revenues. In the event that any of these customers or any other significant customer substantially reduces its purchases of our products, particularly if this occurs without adequate advance notice to enable us to secure alternate importation or distribution arrangements, our results of operations could be materially and adversely affected.

We or our suppliers may experience development or manufacturing problems or delays that could limit the growth of our revenue or increase our losses.

We may encounter unforeseen situations in the manufacture and assembly of our T-SPOT.*TB* test that would result in delays or shortfalls in our production. Our suppliers may also face similar delays or shortfalls. In addition, our or our suppliers' production processes and assembly methods may have to change to accommodate any significant future expansion of our manufacturing capacity, which may increase our or our suppliers' manufacturing costs, delay production of our product, reduce our product margin and adversely impact our business. If we are unable to keep up with demand for our product by successfully manufacturing and shipping our product in a timely manner, our revenue could be impaired, market acceptance for our product could be adversely affected and our customers might instead purchase our competitors' products. In addition, developing manufacturing procedures for new products would require developing specific production processes for those products. Developing such processes could be time consuming, and any unexpected difficulty in doing so can delay the introduction of a product.

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We currently perform our tests for our service offering exclusively in one laboratory in the United Kingdom. If this facility or any future facilities or our equipment are damaged or destroyed, or if we experience a significant disruption in our operations for any reason, our ability to continue to operate our business could be materially harmed.

We currently perform our T-SPOT.*TB* test exclusively in a laboratory facility in Abingdon, England. If this facility or any future facilities are to be damaged, destroyed or otherwise unable to operate, whether due to fire, floods, hurricanes, storms, tornadoes, other natural disasters, employee malfeasance, terrorist acts, power outages, or otherwise, or if performance of our laboratory is disrupted for any other reason, we may not be able to perform our tests or generate test reports as promptly as our customers expect, or possibly not at all. Building or finding a replacement facility could be difficult, expensive and time consuming and any new laboratory would need to satisfy the various certification, accreditation and licensing requirements to which our current laboratory facility is subject. If we are unable to perform our tests or generate test reports within a timeframe that meets our customers' expectations, our business, financial results and reputation could be materially harmed.

As of December 31, 2018, we maintain insurance coverage totaling $17.1 million against damage to our property and equipment and an additional $44.4 million to cover business interruption and research and development restoration expenses, subject to deductibles and other limitations. If we have underestimated our insurance needs with respect to an interruption, however, or if an interruption is not subject to coverage under our insurance policies, we may not be able to cover our losses. Even if we cover our losses, our business, financial results and reputation could be materially harmed.

Failure in our information technology or storage systems could significantly disrupt our operations and our research and development efforts, which could adversely impact our revenue, as well as our research, development and commercialization efforts.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our information technology, or IT, systems, which support our operations, including our Laboratory Information System, or LIS. Due to the sophisticated nature of the technology we use in our laboratory, we are substantially dependent on our IT systems. IT systems are vulnerable to damage from a variety of sources, including telecommunications or network failures, malicious human acts and natural disasters. Moreover, despite network security and back-up measures, some of our servers are potentially vulnerable to physical or electronic break-ins, computer viruses and similar disruptive problems. Despite the precautionary measures we have taken to prevent unanticipated problems that could affect our IT systems, sustained or repeated system failures that interrupt our ability to generate and maintain data, and in particular to operate our LIS or billing systems, could adversely affect our ability to operate our business. Any interruption in the operation of our LIS or other IT systems, due to IT system failures, part failures or potential disruptions in the event we are required to relocate our IT systems within our facility or to another facility could have an adverse effect on our operations.

Because our business relies heavily on international operations and revenue, changes in currency exchange rates and our need to convert currencies may negatively affect our financial condition and results of operations.

Our business relies heavily on our operations outside the United States. For the year ended December 31, 2018, 72% of our total revenue was derived from sales outside the United States. Because we currently operate in three major regions of the world (the United States, Europe and rest of world, or Europe and ROW, and Asia), our revenue is denominated in multiple currencies. Sales in the United States are denominated in U.S. Dollars. Sales in China are denominated in U.S. Dollars and sales in Japan are denominated in Yen but, in each case, these sales are made by our U.K.-based legal entity where the Pound Sterling is the functional currency. As a result, these sales are subject to remeasurement into Pounds Sterling and then translation into U.S. Dollars when we consolidate our financial statements. Sales in Europe are denominated primarily in the Pound Sterling and Euro. As we grow Europe and ROW sales outside the United Kingdom and the European Union countries, or the Euro Zone, whose national currency is the Euro, we will be subject to exchange rate risk from additional currencies. As a result, our exchange rate exposure may change over time as our business practices evolve and could result in increased costs or reduced revenue and could affect our actual cash flow. Changes in the relative values of currencies occur regularly and, in some instances, may have a significant impact on our operating results. We cannot predict with any certainty changes in currency exchange rates or the degree to which we can effectively mitigate these risks.

In addition, the weakening of foreign currencies relative to the U.S. Dollar may require us to reduce prices to allow distributors to maintain profitable businesses. As a result, sales and earnings of our products in countries outside the United States may be materially adversely affected by foreign currency exchange rate fluctuations.

A decline in the state of the global economy and financial market conditions could adversely affect our ability to conduct business and our results of operations.

Global economic and financial market conditions, including disruptions in the credit markets and the threat of or impact of global economic deterioration may materially impact our customers and other parties with whom we do business. Such conditions could negatively affect our future sales of our products. A decline in general economic and financial market conditions could materially adversely affect our financial condition and results of operations. Specifically, the impact of these volatile and negative conditions may include decreased demand for our products and services, a decrease in our ability to accurately forecast future product trends and demand, and a negative impact on our ability to timely collect receivables from our customers. The foregoing economic conditions may lead to increased levels of bankruptcies, restructurings and liquidations for our customers, scaling back of research and development expenditures, delays in planned projects and shifts in business strategies for many of our customers. Such events could, in turn, adversely affect our business through loss of sales.

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Uncertainty arising from global political events, including as a result of the June 2016 referendum on the United Kingdom's exit from the European Union, could adversely affect our ability to conduct business and our results of operations.

On June 23, 2016, the United Kingdom, or U.K., held a non-binding referendum, in which voters approved an exit from the European Union, or E.U., commonly referred to as "Brexit". Thereafter, on March 29, 2017, the U.K. formally notified the E.U. of its intention to withdraw pursuant to Article 50 of the Treaty of the European Union, which formally initiated the withdrawal procedure. A process of negotiation is currently taking place to determine the future terms of the U.K.'s relationship with the E.U., with the U.K. due to exit the E.U. on March 29, 2019.

It appears likely that this withdrawal will involve a process of lengthy negotiations between the U.K. and E.U. member states to determine the future terms of the U.K.'s relationship with the E.U. For example, while the U.K. government and the E.U. had negotiated a withdrawal agreement and the E.U. had approved such withdrawal agreement, the British Parliament subsequently rejected the withdrawal agreement. As a result, there remains considerable uncertainty around the withdrawal. Failure to obtain parliamentary approval of a negotiated withdrawal agreement would mean that the U.K. would leave the E.U. on March 29, 2019 with no agreement (a so-called "hard Brexit"). The ongoing negotiations between the U.K. and E.U., could lead to a period of considerable uncertainty and volatility, particularly in relation to U.K. financial and banking markets. There is also a risk that the vote by the U.K. to leave the E.U. could result in other member states re-considering their respective membership in the E.U. Weakening of economic conditions or economic uncertainties tend to harm our business, and if such conditions emerge in the U.K. or in the rest of Europe, it may have a material adverse effect on our operations and sales.

Although it is unknown what the terms of the U.K.'s future relationship with the E.U. will be, it is possible that there will be greater restrictions on trade between the U.K. and E.U. countries and increased regulatory complexities. These changes may adversely affect our operations and financial results. The announcement of Brexit also caused significant volatility in global currency markets. The fluctuation of currency exchange rates may expose us to gains and losses on non U.S. currency transactions and impact the purchasing power of our non U.S. currency customers, causing them to decrease or cancel orders or default on payment. Any global political uncertainty similar to the Brexit referendum could similarly harm our ability to conduct our business and our results of operations.

Changes in U.S. tax law and international trade relations may have a material adverse effect on our business, financial condition and results of operations.

Changes in laws and policy relating to taxes or trade may have an adverse effect on our business, financial condition and results of operations. Recent tax reforms in the U.S. have resulted in significant changes to preexisting U.S. tax rules and regulations. These changes may trigger an adverse effect on our business, financial conditions and results of operations.

Additionally, the U.S. government may seek to implement more protective trade measures with countries in which we conduct business in, which has introduced a great deal of uncertainty regarding trade policies, tariffs and government regulations, which if altered could have the potential to create a significant adverse effect on trade between the U.S. and other countries. Overall, changes in international trade relations, such as the imposition of or increase in tariffs or other trade barriers, could materially and adversely impact our costs and reduce the competitiveness of our products.

We have in the past and may in the future seek to grow our business through acquisitions of or investments in new or complementary businesses, products or technologies, and the failure to manage acquisitions or investments, or the failure to integrate them with our existing business, could have a material adverse effect on our operating results and the value of our ordinary shares.

From time to time we expect to consider opportunities to acquire or make investments in other technologies, products and businesses that may enhance our capabilities, complement our current products or expand the breadth of our product offerings, markets or customer base. Potential and completed acquisitions and strategic investments involve numerous risks, including:

- difficulties in acquiring new products, technologies or businesses that will help our current business;
- difficulties in integrating acquired personnel, technologies, products or business operations;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our core business;
- adverse effects on existing business relationships with suppliers and customers;
- risks associated with entering new markets in which we have limited or no experience;
- potential loss of key employees of acquired businesses; and
- increased legal and accounting compliance costs.

Further, any acquisitions we undertake in the future could be expensive and time consuming, and may disrupt our ongoing business and prevent management from focusing on our operations. If we are unable to manage acquisitions or investments, or integrate any future acquired businesses, products or technologies effectively, our business, results of operations and financial condition may be materially and adversely affected.

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Write-offs related to the impairments of our long-lived assets, including goodwill and indefinite-lived intangible assets may adversely impact our results of operations.

We have in the past and may in the future need to take write-offs as a result of impairments to certain of our long-lived assets. For example, in the fourth quarter of 2018, due to the Company's change in focus following the Transaction, we recorded a non-cash impairment charge of $879,000 to write-off certain intangible assets acquired in conjunction with the 2016 acquisition of Immunetics. In the third quarter of 2017, due to increased competition in the molecular blood donor screening market for *Babesia microti*, we recorded a non-cash impairment charge of $11.1 million to write-off certain intangible assets acquired in conjunction with the 2016 acquisition of Imugen. Additionally, in the fourth quarter of 2017, due to a mid-February complete response letter, or CRL, from FDA regarding the Company's fourth quarter 2017 submissions in relation to its biological license applications, or BLAs, for the Immunetics *Babesia microti* blood donor screening assay, the Company recorded an impairment charge of $7.2 million to write-off the related intangible assets.

Further, during the fourth quarter of 2016, we made the strategic decision to end our GoutiFind program. GoutiFind was a blood test designed to allow for early diagnosis of gout and better inform therapies by measuring the strength of the underlying uric acid induced inflammation. As a result of this decision, we recorded a non-cash in-process research and development, or IPR&D, impairment charge of $270,000. Also during the fourth quarter of 2016, we recorded a non-cash IPR&D impairment charge of $1.4 million related to the SpiroFind assay when it was determined that the Boulder IPR&D will not directly yield any products.

We may incur additional non-cash charges related to impairments of our long-lived assets, including goodwill. We are required to perform periodic impairment reviews of these assets at least annually. To the extent future reviews conclude that the expected future cash flows generated from our business activities are not sufficient to recover the carrying value of these assets, we will be required to measure and record an impairment charge to write-down these assets to their realizable values and those impairment charges could be equal to the entire carrying value of the assets. Any such write-downs could adversely impact our operating results.

Our business could suffer if we lose the services of, or are unable to attract and retain, key members of our senior management, key advisors or other personnel.

We are dependent upon the continued services of key members of our senior management and a limited number of key advisors and personnel. In particular, we are highly dependent on the skills and leadership of our Chief Executive Officer, Dr. Peter Wrighton-Smith, and the other members of management named in the "Management" section elsewhere in this Annual Report. The loss of any one of these individuals, without adequate time to find a suitable replacement, could disrupt our operations or our strategic plans. Additionally, our future success will depend on, among other things, our ability to continue to hire and retain the necessary qualified scientific, technical, sales, marketing and managerial personnel, for whom we compete with numerous other companies, academic institutions

and organizations. The loss of members of our management team, key advisors or personnel, or our inability to attract or retain other qualified personnel or advisors, could have a material adverse effect on our business, results of operations and financial condition. Although all members of our senior management team have entered into agreements that restrict their ability to compete with us for a period of time after the end of their employment, we may be unable to enforce such restrictive covenants at all or for a sufficient duration of time to prevent members of our management team from competing with us.

Our ability to use net operating losses to offset future taxable income may be subject to substantial limitations.

As of December 31, 2018, our available U.S. federal net operating losses, or NOLs, totaled $54.7 million and U.S. state loss carryforwards totaled $50.3 million. The amount of these NOLs remains subject to review and possible adjustment by the Internal Revenue Service and state revenue authorities, as applicable. NOLs may become subject to an annual limitation if there is a cumulative change in the ownership interest of significant shareholders (or certain shareholder groups) over a three-year period in excess of 50%, in accordance with rules established under Section 382 of the Internal Revenue Code of 1986, as amended, or the Code, and similar state rules (we refer to each as an ownership change). Such an ownership change could limit the amount of historic NOLs that can be utilized annually to offset future taxable income. The amount of this annual limitation is determined based on our value immediately prior to the ownership change. We have completed several financings since our inception, including our most recent public offering of ordinary shares that closed on August 18, 2017, that may have resulted in one or more ownership changes under this definition. If we are deemed to have undergone an ownership change by virtue of these transactions, we may not be able to utilize a material portion of our NOLs even if we attain profitability. Future changes in our share ownership, some of which are outside of our control, could result in additional ownership changes for purposes of these rules. We are unable to predict future ownership changes or the way an ownership change could limit the use of our NOLs. In addition, recent changes to U.S. tax laws could negatively affect our ability to use net operating losses to offset future taxable income.

Unlike in prior years, as of December 31, 2018, we no longer qualified as an "emerging growth company" and will incur significant legal, accounting and other expenses.

We have determined that, as of December 31, 2018, the last day of the fiscal year following the fifth anniversary of our initial public offering in November 2013, we no longer qualified as an "emerging growth company" as defined in the Jumpstart Our Business Startups Act of 2012. Because we no longer qualify as an emerging growth company, and as certain extended transition periods available to emerging growth companies expire, we have become subject to additional reporting requirements and standards and accelerated filing deadlines for our periodic reports. For example, we are now subject to enhanced disclosures obligations regarding executive compensation in our periodic reports and proxy statements and requirements to hold a nonbinding advisory vote on executive compensation. As a result, we have taken steps to implement the systems and processes required to comply with these additional requirements and we have incurred significant legal, accounting and other expenses.

The failure to successfully maintain the adequacy of our system of internal control over financial reporting could have a material adverse impact on our ability to report our financial results in an accurate and timely manner.

Section 404 of the Sarbanes-Oxley Act requires us to evaluate annually the effectiveness of our internal control over financial reporting as of the end of each fiscal year and to include a management report assessing the effectiveness of our internal control over financial reporting in our Annual Report on Form 10-K. Section 404 also requires our independent registered public accounting firm to report on our internal control over financial reporting. If we fail to maintain the adequacy of our internal controls, we cannot assure you that we will be able to conclude in the future that we have effective internal control over financial reporting. If we fail to maintain effective internal controls, including remediating any material weaknesses or deficiencies in our internal controls, as such standards are modified, supplemented or amended in the future, we could be subject to regulatory actions, civil or criminal penalties or shareholder litigation. In addition, failure to maintain adequate internal controls could result in financial statements that do not accurately reflect our financial condition, results of operations and cash flows.

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Our management's assessment of the effectiveness of our internal control over financial reporting, as of December 31, 2018, identified a material weakness in our internal controls relating to tax accounting, primarily as a result of a lack of necessary corporate tax resources and ineffective execution of the review of the tax provision and the deferred tax rollforward. While we intend to take remediation measures to correct this material weakness (which measures are more fully described in Item 9A of this report), we cannot assure that we will not have material weaknesses or significant deficiencies in our internal controls in the future. Any failure in the effectiveness of our system of internal control over financial reporting could have a material adverse impact on our ability to report our financial results in an accurate and timely manner.

Risks related to the sale of our U.S. laboratory services business to Quest.

We will be subject to business uncertainties and contractual restrictions due to the Transaction.

The pursuit of the Transaction and the preparation for the integration of the U.S. laboratory services business with Quest may place a significant burden on our management and internal resources. Any significant diversion of management and employee attention away from our ongoing business and any difficulties encountered in the transition and integration process with Quest may affect our financial results. Our customers, employees, partners and other parties may have uncertainties about the effects of the Transaction. In connection with the Transaction, it is possible that some customers and other persons with whom we have a business relationship may delay or defer certain business decisions or might decide to seek to terminate, change or renegotiate their relationship with us as a result of the Transaction. If any of these effects were to occur, it could materially and adversely impact our revenue, earnings and cash flows and other business results and financial condition, as well as the market price of our ordinary shares.

For more information related to the Transaction, please refer to “Business—Overview”, Note 19. *Discontinued operations* to our consolidated financial statements included in this Annual Report, and also to our “Management’s Discussion and Analysis of Financial Condition and Results of Operations” included in this Annual Report.

The Purchase Agreement exposes us to contingent liabilities that could have a material adverse effect on our financial condition.

We have agreed to indemnify Quest for damages resulting from or arising out of any inaccuracy or breach of our representations, warranties or covenants in the Purchase Agreement, any and all of our liabilities not assumed by Quest in the Transaction and for certain other matters. Pursuant to the Purchase Agreement, other than in the case of damages arising out of actual and intentional fraud of an indemnifying party, in no event will we or Quest be required to indemnify each other for any damages that exceed the final Transaction purchase price of $170 million. Yet, any event that results in a right for Quest to seek indemnity from us could result in a substantial payment from us to Quest

and could have a material adverse effect on our financial condition and results of operations.

Litigation may arise in connection with the Transaction, which could be costly, divert management's attention and otherwise materially harm our business.

Regardless of the outcome of any future litigation related to the Transaction, such litigation may be time-consuming and expensive and may distract our management from running the day-to-day operations of our business. The litigation costs and diversion of management's attention and resources to address the claims and counterclaims in any litigation related to the Transaction may materially adversely affect our business, financial condition and operating results. Any litigation related to the Transaction may result in negative publicity or an unfavorable impression of us, which could adversely affect the price of our ordinary shares, impair our ability to recruit or retain employees, damage our relationships with our customers and suppliers, or otherwise materially harm our operations and financial performance.

Risks related to regulatory and other legal issues.

If we fail to comply with extensive regulations of domestic and international regulatory authorities, sales of our T-SPOT.TB test in new markets and the development and commercialization of any new product candidates could be delayed or prevented.

Our existing tests, as well as new tests will be, subject to extensive government regulations related to development, testing, manufacturing and commercialization in the United States and other countries before we can sell in these markets. The process of obtaining and complying with FDA and other governmental regulatory approvals and regulations is costly, time consuming, uncertain and subject to unanticipated delays. Securing regulatory approval for a new product, in the United States and many other countries, typically requires several years. Despite the time and expense exerted, regulatory approval is never guaranteed. We may not be able to obtain FDA or other required regulatory approval and market any further products we may develop during the time we anticipate, or at all. We also are subject to the following risks and obligations, among others:

- regulators may refuse to approve an application if they believe that applicable regulatory criteria are not satisfied;
- regulators may require additional testing for safety and effectiveness;
- regulators may interpret data from clinical studies in different ways than we interpret them;
- if regulatory approval of a product is granted, the approval may be limited to specific indications or limited with respect to its distribution; and
- regulators may change their approval policies and/or adopt new regulations that affect our ability to secure approvals for new products, which would decrease the chance we would be able to commercialize new diagnostic tests.

In addition, some international jurisdictions, such as China, require periodic recertification. Even if we obtain initial certifications from regulatory bodies, we may lose certification after a periodic review. Failure to maintain requisite certifications from regulatory bodies would adversely affect our ability to generate future revenue and operating

income.

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If we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any product for which we obtain marketing approval in the United States or in international jurisdictions, along with the manufacturing processes, post-approval clinical data and promotional activities for such product, will be subject to continual review and periodic inspections by the FDA and other regulatory bodies. Furthermore, our suppliers may be subject to similar regulatory oversight, and may not currently be or may not continue to be in compliance with applicable regulatory requirements. Failure by us or one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or failure to take adequate action in response to any observations, could result in, among other things, any of the following enforcement actions:

- warning letters or untitled letters;
- fines and civil penalties;
- unanticipated expenditures for corrective actions;
- delays in approving, or refusal to approve, our products;
- withdrawal or suspension of approval by the FDA or other regulatory bodies;
- product recall or seizures;
- interruption of production;
- operating restrictions;
- injunctions; and
- criminal penalties.

If any of these actions were to occur, it could harm our reputation and could cause our product sales and profitability to suffer.

Any regulatory approval of a product may also be subject to limitations on the indicated uses for which the product may be marketed. If the FDA or another regulatory body determines that our promotional materials, training or other activities constitute promotion of an unapproved use, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our training or promotional materials to constitute promotion of an unapproved use, which could result in significant fines or penalties under applicable statutory authorities, such as laws prohibiting false claims for reimbursement.

Additionally, we may be required to conduct costly post-market testing, and we will be required to report adverse events and malfunctions related to our products. Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements may result in restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties.

Furthermore, the FDA and various other authorities will inspect our facilities and those of our suppliers from time to time to determine whether we are in compliance with regulations relating to the manufacture of diagnostic products, including regulations concerning design, manufacture, testing, quality control, product labeling, distribution, promotion and record-keeping practices. A determination that we are in material violation of such regulations could lead to the imposition of civil penalties, including fines, product recalls, product seizures or, in extreme cases, criminal sanctions.

We may potentially be subject to product liability claims.

The testing, manufacturing and marketing of medical diagnostic tests such as our T-SPOT.*TB* test entail an inherent risk of product liability claims. Further, providing clinical testing services entails a risk of claims for errors or omissions made by our laboratory staff. Potential liability claims may exceed the amount of our insurance coverage or may be excluded from coverage under the terms of the policy. As of December 31, 2018, we had product liability insurance of $14.4 million. Our existing insurance will have to be increased in the future if we are successful at introducing new diagnostic products and this will increase our costs. Under certain of our customer and license agreements, we have agreed to provide indemnification for product liability claims arising out of the use of our T-SPOT.*TB* test. In the event that we are held liable for a claim or for damages exceeding the limits of our insurance coverage, we may be required to make substantial payments.

Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for our product and product candidates;
- injury to our reputation;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenue; and
- the inability to commercialize our products and product candidates.

Any of these outcomes may have an adverse effect on our consolidated results of operations, financial condition and cash flows, and may increase the volatility of our share price.

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Our inadvertent or unintentional failure to comply with the complex government regulations concerning privacy of medical and personal information could subject us to fines and adversely affect our reputation.

Privacy regulations in the U.S. and around the world limit use or disclosure of protected personal information without written authorization or consent, except for permitted purposes outlined in the privacy regulations. The privacy regulations provide for significant fines and other penalties for wrongful use or disclosure of protected health information, including potential civil and criminal fines and penalties.

We have policies and practices that we believe make us compliant with the privacy regulations. Nevertheless, the documentation and process requirements of the privacy regulations are complex and subject to interpretation. Failure to comply with the privacy regulations could subject us to sanctions or penalties, loss of business and negative publicity.

In the U.S., the privacy regulations establish a “floor” of minimum protection for patients as to their medical information. We are required to comply with both HIPAA privacy regulations and various state privacy laws. Although the HIPAA statute and regulations do not expressly provide for a private right of action, we could incur damages under state laws to private parties for the wrongful use or disclosure of confidential health information or other private personal information. Internationally, virtually every jurisdiction in which we operate has established its own data security and privacy legal framework with which we or our customers must comply, including the General Data Protection Regulation established in the European Union. We may also need to comply with varying and possibly conflicting privacy laws and regulations in other jurisdictions. As a result, we could face regulatory actions, including significant fines or penalties, adverse publicity and possible loss of business.

A disruption in our computer networks, including those related to cybersecurity, could adversely affect our financial performance.

Cybersecurity refers to the combination of technologies, processes and procedures established to protect information technology systems and data from unauthorized access, attack, or damage. We rely on our computer networks and systems, some of which are managed by third parties, to manage and store electronic information (including sensitive data such as confidential business information and personally identifiable data relating to employees, customers and other business partners), and to manage or support a variety of critical business processes and activities. Cyber-attacks are increasingly more common, including in the health care industry. The regulatory environment surrounding information security and privacy is increasingly demanding, with the frequent imposition of new and changing requirements. Compliance with changes in privacy and information security laws and with rapidly evolving industry standards may result in our incurring significant expense due to increased investment in technology and the development of new operational processes.

We have not experienced any known attacks on our information technology systems that have resulted in any material system failure, accident or security breach to date. However, we may face threats to our networks from unauthorized access, security breaches and other system disruptions. We maintain our information technology systems with safeguard protection against cyber-attacks, including passive intrusion protection, firewalls and virus detection software. However, these safeguards do not ensure that a significant cyber-attack could not occur. Although we have taken steps to protect the security of our information systems and the data maintained in those systems, it is possible that our safety and security measures will not prevent the systems' improper functioning or damage or the improper access or disclosure of personally identifiable information such as in the event of cyber-attacks.

Security breaches, including physical or electronic break-ins, computer viruses, attacks by hackers and similar breaches can create system disruptions or shutdowns or the unauthorized disclosure of confidential information. If personal information or protected health information is improperly accessed, tampered with or disclosed as a result of a security breach, we may incur significant costs to notify and mitigate potential harm to the affected individuals, and we may be subject to sanctions and civil or criminal penalties if we are found to be in violation of the privacy or security rules under HIPAA or other similar federal or state laws protecting confidential personal information. In addition, a cybersecurity breach could hurt our reputation by adversely affecting the perception of customers and potential customers of the security of their orders and personal information, subject us to liability claims or regulatory penalties for compromised personal information and could have a material adverse effect on our business, financial condition and results of operations.

Our use of biological and hazardous materials and waste requires us to comply with regulatory requirements, including environmental, health and safety laws, regulations and permit requirements and subjects us to significant costs and exposes us to potential liabilities.

The handling of materials used in the diagnostic testing process involves the controlled use of biological and hazardous materials and wastes. The primary hazardous materials we handle or use include human blood samples and solvents. Our business and facilities and those of our suppliers are subject to federal, state, local and foreign laws and regulations relating to the protection of human health and the environment, including those governing the use, manufacture, storage, handling and disposal of, and exposure to, such materials and wastes. In addition, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations, including the failure to obtain, maintain or comply with any required permits, could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations and financial condition. In addition, we may be required to incur significant costs to comply with regulatory requirements in the future.

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Our business arrangements with customers are subject to applicable anti-kickback, anti-fraud and abuse and other healthcare laws and regulations. If such business arrangements fail to comply with these laws and regulations, we could be exposed to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers and physicians play a primary role in the recommendation and ordering of any product candidates, including our T-SPOT.*TB* test, for which we obtain marketing approval. Our arrangements with customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The U.S. federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others. Several other countries, including the United Kingdom, have enacted similar anti-kickback, fraud and abuse, and healthcare laws and regulations.
- The U.S. False Claims Act imposes criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government.
- HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. HIPAA also imposes criminal liability for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.
- The federal Physician Payment Sunshine Act requirements under the PPACA require manufacturers of drugs, devices, biologics and medical supplies to report to HHS information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law. Certain state laws and regulations also require the reporting of certain items of value provided to health care professionals.
- Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. We may be subject to *qui tam* litigation brought by private individuals on behalf of the government under the U.S. Federal False Claims Act, which would include claims for up to treble damages. Additionally, it is possible that governmental authorities would conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Exclusion, suspension and debarment from government funded

healthcare programs would significantly impact our ability to commercialize, sell or distribute any product. If any of the physicians or other providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

We are subject to the U.K. Bribery Act, the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties, other remedial measures, and legal expenses, which could adversely affect our business, results of operations and financial condition.

Our operations are subject to anti-corruption laws, including the U.K. Bribery Act 2010, or Bribery Act, the U.S. Foreign Corrupt Practices Act, or FCPA, and other anti-corruption laws that apply in countries where we do business. The Bribery Act, FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We and our commercial partners operate in a number of jurisdictions that pose a high risk of potential Bribery Act or FCPA violations, and we participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under the Bribery Act, FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

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We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United Kingdom and the United States, and authorities in the European Union, including applicable export control regulations, economic sanctions on countries and persons, customs requirements and currency exchange regulations, collectively referred to as the Trade Control laws.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws, including the Bribery Act, the FCPA or other legal requirements, including Trade Control laws. If we violate provisions of the Bribery Act, the FCPA or other anti-corruption laws or Trade Control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our business, financial condition, results of operations and liquidity. Likewise, any investigation into or audit of us of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by U.K., U.S. or other authorities could subject us to fines or criminal or other penalties, which could have an adverse impact on our reputation, our business, results of operations and financial condition.

Healthcare reform measures could hinder or prevent the commercial success of our diagnostic tests.

In March 2010, President Obama signed into law a legislative overhaul of the U.S. healthcare system, the PPACA, which had far-reaching consequences for many healthcare companies, including diagnostic companies like us. For example, if reimbursement for our diagnostic tests is substantially less than we or our clinical laboratory customers expect, our business could be materially and adversely impacted. However, the future of the PPACA is uncertain and at this juncture there will be a period of uncertainty regarding the PPACA's repeal, modification or replacement or the effect of the changes made to the PPACA under the Tax Cuts and Jobs Act of 2017, any of which could have long term financial impact on the delivery of and payment for healthcare in the U.S.

Regardless of the impact of the PPACA on us, the U.S. government and other governments have shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could cause significant pressure on the pricing of healthcare products and services, including our T-SPOT.*TB* test, in the United States and internationally, as well as the amount of reimbursement available from governmental agencies and other third-party payors.

Actual and anticipated changes to the regulations of the healthcare system and U.S. tax laws may have a negative impact on the cost of healthcare coverage and reimbursement of healthcare services and products.

The FDA and comparable agencies in other jurisdictions directly regulate many critical activities of life science, technology, and healthcare industries, including the conduct of preclinical and clinical studies, product manufacturing, advertising and promotion, product distribution, adverse event reporting, and product risk management. In both

domestic and foreign markets, sales of products depend in part on the availability and amount of reimbursement by third-party payors, including governments and private health plans. Governments may regulate coverage, reimbursement, and pricing of products to control cost or affect utilization of products. Private health plans may also seek to manage cost and utilization by implementing coverage and reimbursement limitations. Substantial uncertainty exists regarding the reimbursement by third-party payors of newly approved healthcare products. The U.S. and foreign governments regularly consider reform measures that affect healthcare coverage and costs. Such reforms may include changes to the coverage and reimbursement of healthcare services and products. In particular, there have been recent judicial and Congressional challenges to the PPACA, which could have an impact on coverage and reimbursement for healthcare services covered by plans authorized by the PPACA, and we expect there will be additional challenges and amendments to the PPACA in the future.

Attempts to repeal or to repeal and replace the PPACA will likely continue under the current Congress. In addition, various other healthcare reform proposals have emerged at the federal and state level. The recent changes to U.S. tax laws could also negatively impact the PPACA. We cannot predict what healthcare initiatives or tax law changes, if any, will be implemented at the federal or state level, however, government and other regulatory oversight and future regulatory and government interference with the healthcare systems could adversely impact our business.

Risks related to our intellectual property.

We may be unable to protect or obtain proprietary rights that we utilize or intend to utilize.

In developing, manufacturing and using our T-SPOT.*TB* test, we employ a variety of proprietary and patented technologies, including technologies we license from third parties. We have licensed, and expect to continue to license, various other technologies and methods. We cannot provide any assurance that the intellectual property rights that we own or license provide protection from competitive threats or that we would prevail in any challenge mounted to our intellectual property rights. See “Legal Proceedings” for more information. In addition, we cannot provide any assurances that we will be successful in obtaining and retaining licenses or proprietary or patented technologies in the future.

We are unable to predict whether any of our currently pending or future patent applications will result in issued patents, or how long it may take for such patents to be issued. Further, we cannot predict whether other parties will challenge any patents issued or licensed to us or that courts or administrative agencies will hold our patents or the patents we license to be valid and enforceable. We may not be successful in defending challenges made against our patents and patent applications. Any successful third-party challenge to our patents could result in the unenforceability or invalidity of such patents. Both the patent application process and the process of managing patent disputes can be time consuming and expensive.

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The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. Furthermore, in the biotechnology field, courts frequently render opinions that may affect the patentability of certain inventions or discoveries and the patent positions of companies engaged in development and commercialization of certain diagnostic tests. Various courts, including the U.S. Supreme Court, have recently rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to genomic diagnostics. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize the law of nature itself. What constitutes a "sufficient" additional feature is uncertain. While we do not generally rely on gene sequence patents, this evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and licensed patents.

Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property rights. We cannot predict the breadth of claims that may be allowed or enforced in patents we own or in those to which we have license rights. For example:

- the inventor might not have been the first to make the inventions covered by patents we rely on;
- the inventor or his assignee might not have been the first to file patent applications for the claimed inventions;
- others may independently develop similar or alternative products and technologies or duplicate our product and technologies;
- it is possible that the patents we own or license may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- any patents we obtain or license may expire before, or shortly after, the products and services relating to such patents are commercialized;
- we may not develop additional proprietary products and technologies that are patentable; and
- the patents of others may have an adverse effect on our business.

In particular, in September 2011, the U.S. Congress passed the Leahy-Smith America Invents Act, or the AIA, which became effective in March 2013. The AIA reforms U.S. patent law in part by changing the standard for patent approval for certain patents from a "first to invent" standard to a "first to file" standard and developing a post-grant review system. It is too early to determine what the effect or impact the AIA will have on the operation of our business and the protection and enforcement of our intellectual property. However, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents, all of which could have a material adverse effect on our business and financial condition.

Some patent applications in the United States may be maintained in secrecy until the patents are issued, other patent applications in the United States and many foreign jurisdictions are not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries. We therefore cannot be certain that others have not filed patent applications for technology covered by issued patents or pending applications that we own or license or that we or our licensors, as applicable, were the first to invent the technology (pre-AIA) or first to file (post-AIA). Our competitors may have filed, and may in the future file, patent applications covering technology

similar or the same as ours. Any such patent application may have priority over patent applications that we own or license and could further require us to obtain rights to such technologies in order to carry on our business. If another party has filed a U.S. patent application on inventions similar or the same as those that we own or license, we or our licensors may have to participate in an interference or other proceeding in the U.S. Patent and Trademark Office, or PTO, or a court to determine priority of invention in the United States, for pre-AIA applications and patents. For post-AIA applications and patents, we or our licensors may have to participate in a derivation proceeding to resolve disputes relating to inventorship. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent disputes and litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any disputes or litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

In addition to pursuing patents on our technology, we seek to protect our intellectual property and proprietary technology by entering into intellectual property assignment agreements with our employees, consultants and third-party collaborators. See “We may be unable to adequately prevent disclosure of trade secrets and other proprietary information, or the misappropriation of the intellectual property we regard as our own.”

Our intellectual property rights may not be sufficient to protect our competitive position and to prevent others from manufacturing, using or selling competing products.

The scope of our owned and licensed intellectual property rights may not be sufficient to prevent others from manufacturing, using or selling competing tests. For example, our intellectual property position depends in part on intellectual property that we license from third parties. However, many of the key patents we license are expected to expire by 2020. In addition, while many of the licenses we have been granted are exclusive, such rights may be limited to a narrowly defined field of use. As a result, our competitors may have obtained or be able to obtain a license to the same intellectual property in a closely related field of use. Finally, we have also granted sublicenses to third parties under certain of the intellectual property that we license. Such sublicenses may allow third parties or their licensees to market a TB test that would otherwise infringe upon such intellectual property.

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Moreover, competitors could purchase our product and attempt to replicate some or all of the competitive advantages we derive from our development efforts, willfully infringe our intellectual property rights, design around our protected technology or develop their own competitive technologies that fall outside of our intellectual property rights. If our intellectual property is not adequately protected so as to protect our market against competitors' products and methods, our competitive position could be adversely affected, as could our business.

We depend on certain technologies that are licensed or sublicensed to us. We do not control these technologies and any loss of our rights to them could prevent us from selling our product.

We rely on licenses in order to be able to use various proprietary technologies that are material to our business. We do not own the patents that underlie these licenses. Our rights to use these technologies and employ the inventions claimed in the licensed patents are subject to the continuation of and our compliance with the terms of those licenses.

In some cases, we do not control the prosecution, maintenance or filing of the patents to which we hold licenses. Enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents is often subject to the control or cooperation of our licensors. We cannot be certain that our licensors will prosecute, maintain, enforce and defend the licensed patent rights in a manner consistent with the best interests of our business. We also cannot be certain that drafting or prosecution of the licensed patents and patent applications by the licensors have been or will be conducted in compliance with applicable laws and regulations, will result in valid and enforceable patents and other intellectual property rights, or that any issued patents or patents that may issue in the future will provide any competitive advantage.

Certain of our licenses contain provisions that allow the licensor to terminate the license upon specific conditions. Our rights under each of the licenses are subject to our continued compliance with the terms of the license, including certain diligence, disclosure and confidentiality obligations and the payment of royalties and other fees. If we were found to be in breach of any of our license agreements, in certain circumstances our licensors may take action against us, including termination of the applicable license. Because of the complexity of our product and the patents we have licensed, determining the scope of the license and related obligations can be difficult and can lead to disputes between us and the licensor. An unfavorable resolution of such a dispute could lead to an increase in the royalties payable pursuant to the license or termination of the license. If a licensor believed we were not paying the royalties due under the license or were otherwise not in compliance with the terms of the license, the licensor may have the right to terminate the license or, in certain circumstances, to convert an exclusive license to a non-exclusive one. If such an event were to occur, the value of our product or product candidates could be materially adversely affected, we might be barred from producing and selling some or all of our products and may be subject to other liabilities.

In addition to the above risks, certain of our licensors do not own certain intellectual property included in the license, but instead have licensed such intellectual property from a third party, and have granted us a sub-license. As a result, the actions of our licensors or of the ultimate owners of the intellectual property may affect our rights to use our

sublicensed intellectual property, even if we are in compliance with all of the obligations under our license agreements. For example, one of our licenses comprises a sublicense to us of certain patent rights owned by a third party that is not our direct licensor. If our licensors were to fail to comply with their obligations under the agreements pursuant to which they obtain the rights that are sublicensed to us, or should such agreements be terminated or amended, our ability to produce and sell our product and product candidates may be materially harmed. Finally, the legal issues surrounding the treatment of intellectual property licenses in bankruptcy proceedings are complex and may vary from jurisdiction to jurisdiction. We therefore cannot provide assurance that we would not lose some or all of our rights under a license if the applicable licensor was involved in such proceedings.

We may become involved in disputes relating to our intellectual property rights, and may need to resort to litigation in order to defend and enforce our intellectual property rights. In addition, we could face claims that our activities or the manufacture, use or sale of our products infringe the intellectual property rights of others, which could cause us to pay substantial damages or licensing fees and limit our ability to sell some or all of our products and services.

Extensive litigation regarding patents and other intellectual property rights has been common in the medical diagnostics industry. Litigation may be necessary to assert infringement claims, enforce patent rights, protect trade secrets or know-how and determine the enforceability, scope and validity of certain proprietary rights. Litigation may even be necessary to resolve disputes of inventorship or ownership of proprietary rights. The defense and prosecution of intellectual property lawsuits, PTO interference or derivation proceedings, and related legal and administrative proceedings (e.g., a reexamination) in the U.S. and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time consuming to pursue, and their outcome is uncertain.

Even if we prevail in such a proceeding, the remedy we obtain may not be commercially meaningful or adequately compensate us for any damages we may have suffered. If we do not prevail in such a proceeding, certain of our patents could potentially be declared to be invalid, unenforceable or narrowed in scope, or we could otherwise lose valuable intellectual property rights. Similar proceedings involving the intellectual property we license could also have an impact on our business. For example, the scope of one of the European patents that we license from Rutgers, The State University of New Jersey, was narrowed as a result of a third-party opposition proceeding before the European Patent Office. The decision is currently under appeal and the outcome of that appeal may adversely affect our competitive position. Further, if any of our other owned or licensed patents are declared invalid, unenforceable or narrowed in scope, our competitive position could be adversely affected.

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In addition, our research, development and commercialization activities, including our T-SPOT.*TB* test, may infringe or be claimed to infringe patents or other intellectual property rights owned by other parties. Certain of our competitors and other companies have substantial patent portfolios, and may attempt to use patent litigation as a means to obtain a competitive advantage or to extract licensing revenue. The risks of being involved in such litigation may also increase as we gain greater visibility as a public company and as we gain commercial acceptance of our products and move into new markets and applications for our products. There may also be patents and patent applications that are relevant to our technologies or tests that we are not aware of. For example, certain relevant patent applications may have been filed but not published. If such patents exist, or if a patent issues on any of such patent applications, that patent could be asserted against us. In addition to patent infringement claims, we may also be subject to other claims relating to the violation of intellectual property rights, such as claims that we have misappropriated trade secrets or infringed third-party trademarks.

Regardless of merit or outcome, our involvement in any litigation, interference or other administrative proceedings could cause us to incur substantial expense and could significantly divert the efforts of our technical and management personnel. Any public announcements related to litigation or interference proceedings initiated or threatened against us could cause our share price to decline. An adverse determination, or any actions we take or agreements we enter into in order to resolve or avoid disputes, may subject us to the loss of our proprietary position or to significant liabilities, or require us to seek licenses that may include substantial cost and ongoing royalties. Licenses may not be available from third parties, or may not be obtainable on satisfactory terms. An adverse determination or a failure to obtain necessary licenses may restrict or prevent us from manufacturing and selling our products and offering our services. These outcomes could materially harm our business, financial condition and results of operations.

We may not be able to adequately protect our intellectual property outside of the United States.

The laws of some foreign countries do not protect intellectual property rights to the same extent as the laws of the United States, and many companies have encountered significant problems in protecting and defending such rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biotechnology, which could make it difficult for us to stop the infringement of our licensed and owned patents. For example, we are aware that third parties, particularly in China, are currently selling TB diagnostic products that we believe are covered by certain patents we license. We do not know whether our licensor will take all necessary steps to enforce its patent rights in China or whether it will obtain effective relief to stop the sale of products that infringe on its patent rights. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Additionally, prosecuting and maintaining intellectual property (particularly patent) rights are very costly endeavors, and for these and other reasons we may not pursue or obtain patent protection in all major markets. We do not know whether legal and government fees will increase substantially and therefore are unable to predict whether cost may factor into our global intellectual property strategy.

In addition to the risks associated with patent rights, the laws in some foreign jurisdictions may not provide protection for our trade secrets and other intellectual property. If our trade secrets or other intellectual property are

misappropriated in foreign jurisdictions, we may be without adequate remedies to address these issues. Additionally, we also rely on confidentiality and assignment of invention agreements to protect our intellectual property in foreign jurisdictions. These agreements may provide for contractual remedies in the event of misappropriation, but we do not know to what extent, if any, these agreements and any remedies for their breach, will be enforced by a foreign court. In the event our intellectual property is misappropriated or infringed upon and an adequate remedy is not available, our future prospects will likely diminish. The sale of products that infringe our intellectual property rights, particularly if such products are offered at a lower cost, could negatively impact our ability to achieve commercial success and may materially and adversely harm our business.

Our failure to secure trademark registrations could adversely affect our business and our ability to market our product and product candidates.

Our trademark applications in the United States and any other jurisdictions where we may file may not be allowed for registration, and our registered trademarks may not be maintained or enforced. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the PTO and in corresponding foreign agencies, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our applications and/or registrations, and our applications and/or registrations may not survive such proceedings. Failure to secure such trademark registrations in the United States and in foreign jurisdictions could adversely affect our business and our ability to market our product and product candidates.

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Obtaining and maintaining our patent protection depends upon compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The PTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other provisions during the patent prosecution process and following the issuance of a patent. There are situations in which noncompliance with these requirements 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. In such an event, competitors might be able to enter the market earlier than would otherwise have been the case if our patent were in force.

We may be unable to adequately prevent disclosure of trade secrets and other proprietary information, or the misappropriation of the intellectual property we regard as our own.

We rely on trade secrets to protect our proprietary know-how and technological advances, particularly where we do not believe patent protection is appropriate or obtainable. Nevertheless, trade secrets are difficult to protect. We rely in part on confidentiality agreements with our employees, consultants, third-party collaborators and other advisors to protect our trade secrets and other proprietary information. These agreements generally require that the other party to the agreement 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 may not effectively prevent disclosure of confidential information and may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Monitoring unauthorized disclosure is difficult, and we do not know whether the steps we have taken to prevent such disclosure are, or will be, adequate. If we were to seek to pursue a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. Further, courts outside the United States may be less willing to protect trade secrets. In addition, others may independently discover our trade secrets and proprietary information. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our proprietary rights. In addition, our trade secrets and proprietary information may be misappropriated as a result of breaches of our electronic or physical security systems in which case we may have no legal recourse. Failure to obtain, or maintain, trade secret protection could enable competitors to use our proprietary information to develop products that compete with our product or cause additional, material adverse effects upon our competitive business position.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the medical diagnostics industry, we employ individuals who were previously employed at other medical diagnostics companies, including our competitors or potential competitors. We may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information

of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management.

Risks related to our ordinary shares.

Our share price may be volatile.

Like other medical diagnostic companies, the market price of our ordinary shares may be volatile. The factors below may also have a material adverse effect on the market price of our ordinary shares:

- fluctuations in our results of operations;
- our ability to enter new markets;
- negative publicity;
- changes in securities or industry analyst recommendations regarding our company, the sectors in which we operate, the securities market generally and conditions in the financial markets;
- regulatory developments affecting our industry;
- announcements of studies and reports relating to our products or those of our competitors;
- changes in economic performance or market valuations of our competitors;
- actual or anticipated fluctuations in our quarterly results;
- conditions in the industries in which we operate;
- announcements by us or our competitors of new products, acquisitions, strategic relations, joint ventures or capital commitments;
- additions to or departures of our key executives and employees;
- fluctuations of exchange rates;
- release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares; and
- sales or perceived sales of additional shares of our ordinary shares.

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In addition, the equity markets have recently experienced significant volatility, particularly with respect to the securities of life sciences companies. The volatility of the securities of life sciences companies often does not relate to the operating performance of those companies. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. In the past, securities class action litigation has often been initiated against companies following periods of volatility in their stock price. This type of litigation could result in substantial costs and divert our management's attention and resources, and could also require us to make substantial payments to satisfy judgments or to settle litigation.

While we have announced that our Board of Directors has approved a share repurchase program, we cannot guarantee that we will repurchase our ordinary shares pursuant to our share repurchase program or that our share repurchase program will enhance long-term shareholder value.

In January 2019, our Board of Directors announced that it would seek the shareholders' authorization of a share repurchase program. Specifically, the Company intends to seek the shareholders' authorization of the purchase of up to $100 million of the Company's outstanding ordinary shares over a five-year period. The share repurchase program will be presented for shareholder approval on or before our annual general meeting of shareholders on Tuesday, June 18, 2019.

Although our Board of Directors has authorized the share repurchase program, the share repurchase program is subject to shareholder approval, and shareholders may not approve our share repurchase program. Even if we receive shareholder approval of our share repurchase program, our share repurchase program would not obligate us to repurchase any specific dollar amount or to acquire any specific number of shares. The timing and amount of repurchases, if any, will depend upon several factors, including market and business conditions, the trading price of our ordinary shares and the nature of other investment opportunities. The repurchase program may be limited, suspended or discontinued at any time without prior notice.

In addition, repurchases of our ordinary shares pursuant to our share repurchase program could affect our share price and increase its volatility. The existence of a share repurchase program could cause our share price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our ordinary shares. Additionally, our share repurchase program could diminish our cash reserves, which may impact our ability to finance future growth and to pursue possible future strategic opportunities and acquisitions. There can be no assurance that any share repurchases will enhance shareholder value because the market price of our ordinary shares may decline below the levels at which we repurchased shares of stock. Although our share repurchase program is intended to enhance long-term shareholder value, there is no assurance that it will do so and short-term price fluctuations in our ordinary shares could reduce the program's effectiveness.

We do not intend to pay cash dividends on our ordinary shares in the foreseeable future.

We have never paid dividends on ordinary shares and do not currently anticipate paying any cash dividends on our ordinary shares in the foreseeable future. Under English law, any payment of dividends would be subject to relevant legislation and our articles of association, which provide that all dividends must be approved by our Board of Directors and, in some cases, our shareholders, and may only be paid from our distributable profits available for the purpose, determined on an unconsolidated basis.

Our executive officers, directors, and 5% or greater shareholders and management own a significant percentage of our ordinary shares and will be able to exercise significant influence over matters subject to shareholder approval.

Our executive officers, directors, and 5% or greater shareholders beneficially own a substantial percentage of our ordinary shares. For example, as of April 16, 2018, as disclosed in our 2018 Definitive Proxy filed with the SEC on April 27, 2018, our executive officers, directors, and 5% or greater shareholders and their affiliates beneficially owned approximately 48% of our outstanding ordinary shares in the aggregate. We expect that these shareholders will be able to exert a significant degree of influence over our management and affairs and over matters requiring shareholder approval, including the election of our Board of Directors and approval of significant corporate transactions. This concentration of ownership could have the effect of entrenching our management and/or our Board of Directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our ordinary shares.

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Our ordinary shares are listed on The NASDAQ Global Market, but we cannot guarantee that we will be able to satisfy the continued listing standards going forward.

Although our ordinary shares are listed on The NASDAQ Global Market, we cannot ensure that we will be able to satisfy the continued listing standards of The NASDAQ Global Market going forward. If we cannot satisfy the continued listing standards going forward, The NASDAQ Stock Market may commence delisting procedures against us, which could result in our ordinary shares being removed from listing on The NASDAQ Global Market. If our ordinary shares were to be delisted, the liquidity of our ordinary shares could be adversely affected and the market price of our ordinary shares could decrease. Delisting could also adversely affect our shareholders' ability to trade or obtain quotations on our shares because of lower trading volumes and transaction delays. These factors could contribute to lower prices and larger spreads in the bid and ask price for our ordinary shares. Our shareholders may also not be able to resell their shares at or above the price paid for such shares or at all.

English law and provisions in our articles of association may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders, and may prevent attempts by our shareholders to replace or remove our current management.

Certain provisions of English law and our articles of association may have the effect of delaying or preventing a change in control of us or changes in our management. For example, English law and our articles of association include provisions that:

- create a classified Board of Directors whose members serve staggered three-year terms;
- prohibit shareholder action by written resolution;
- establish an advance notice procedure for shareholder approvals to be brought before an annual meeting of our shareholders, including proposed nominations of persons for election to our Board of Directors; and
- provide that vacancies on our Board of Directors may be filled only by a majority of directors then in office, even though less than a quorum.

These provisions, alone or together, could delay or prevent hostile takeovers and changes in control or changes in our management. See also "Provisions in the U.K. City Code on Takeovers and Mergers may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders."

Our holding company structure makes us dependent on the operations of our subsidiaries to meet our financial obligations.

We are a public limited company organized under the laws of England and Wales and have no significant assets other than our interest in Oxford Immunotec Limited and its subsidiaries. As a result, we rely exclusively upon payments,

dividends and distributions from our direct and indirect subsidiaries for our cash flows. Our ability to pay dividends to our shareholders is dependent on the ability of our subsidiaries to generate sufficient net income and cash flows to pay upstream dividends and make loans or loan repayments. However, we have never paid dividends on ordinary shares and do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future.

Risks related to being an English company listing ordinary shares.

U.S. investors may have difficulty enforcing civil liabilities against our company, our directors or members of senior management.

We are incorporated under the laws of England and Wales. The rights of holders of our ordinary shares are governed by English law, including the provisions of the Companies Act 2006, and by our articles of association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations organized in Delaware. Many of our directors and officers reside outside the United States, and a substantial portion of our assets and all or a substantial portion of the assets of such persons are located outside the United States. As a result, it may be difficult for you to serve legal process on us or our directors and executive officers or have any of them appear in a U.S. court. The United States and the United Kingdom do not currently have a treaty providing for the recognition and enforcement of judgments, other than arbitration awards, in civil and commercial matters. The enforceability of any judgment of a U.S. federal or state court in the United Kingdom will depend on the laws and any treaties in effect at the time, including conflicts of laws principles (such as those bearing on the question of whether a U.K. court would recognize the basis on which a U.S. court had purported to exercise jurisdiction over a defendant). In this context, there is doubt as to the enforceability in the United Kingdom of civil liabilities based solely on the federal securities laws of the United States. In addition, awards for punitive damages in actions brought in the United States or elsewhere may be unenforceable in the United Kingdom. An award for monetary damages under the U.S. securities laws would likely be considered punitive if it did not seek to compensate the claimant for loss or damage suffered and was intended to punish the defendant.

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Provisions in the U.K. City Code on Takeovers and Mergers may have anti-takeover effects that could discourage an acquisition of us by others, even if an acquisition would be beneficial to our shareholders.

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 (or the Channel Islands or the Isle of Man) and whose securities are not admitted to trading on a regulated market in the United Kingdom (or the Channel Islands or the Isle of Man) if the company is considered by the Panel on Takeovers and Mergers, or the Takeover Panel, to have its place of central management and control in the United Kingdom (or the Channel Islands or the Isle of Man). This is known as the "residency test." The test for central management and control under the Takeover Code is different from that used by the U.K. tax authorities. Under the Takeover Code, the Takeover Panel will determine whether we have our place of central management and control in the United Kingdom by looking at various factors, including the structure of our Board of Directors, the functions of the directors and where they are resident.

If at the time of a takeover offer the Takeover Panel determines that we have our place of central management and control in the United Kingdom, we would be subject to a number of rules and restrictions, including but not limited to the following: (1) our ability to enter into deal protection arrangements with a bidder would be extremely limited; (2) we might not, without the approval of our shareholders, be able to perform certain actions that could have the effect of frustrating an offer, such as issuing shares or carrying out acquisitions or disposals; and (3) we would be obliged to provide equality of information to all bona fide competing bidders.

If we are a passive foreign investment company, U.S. investors in our ordinary shares could be subject to adverse U.S. federal income tax consequences.

The rules governing passive foreign investment companies, or PFICs, can have adverse effects for U.S. federal income tax purposes. The tests for determining PFIC status for a taxable year depend upon the relative values of certain categories of assets and the relative amounts of certain kinds of income. We do not believe that we are currently a PFIC, and we do not anticipate becoming a PFIC in the foreseeable future. Notwithstanding the foregoing, the determination of whether we are a PFIC depends on the particular facts and circumstances (such as the valuation of our assets, including goodwill and other intangible assets) and may also be affected by the application of the PFIC rules, which are subject to differing interpretations. The fair market value of our assets is expected to depend, in part, upon (a) the market price of our ordinary shares and (b) the composition of our income and assets, which will be affected by how, and how quickly, we spend any cash that is raised in any financing transaction. In light of the foregoing, no assurance can be provided that we are not currently a PFIC or that we will not become a PFIC in any future taxable year.

If we are a PFIC, U.S. holders of our ordinary shares 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. Whether or not U.S. holders of our ordinary shares make a timely qualified electing fund, or QEF, election or mark-to-market election may affect the U.S. federal income tax consequences to U.S. holders with respect to the acquisition, ownership and disposition of our ordinary shares and any distributions such U.S. holders may receive. Investors should consult their own tax advisors regarding all aspects of the application of the PFIC rules to our ordinary shares.

U.S. holders of 10% or more of the voting power of our ordinary shares may be subject to U.S. federal income taxation at ordinary income tax rates on undistributed earnings and profits.

There is a risk that we will be classified as a controlled foreign corporation, or CFC, for U.S. federal income tax purposes. We will generally be classified as a CFC if more than 50% of our outstanding shares, measured by reference to voting power or value, are owned (directly, indirectly or by attribution) by "U.S. Shareholders." For this purpose, a "U.S. Shareholder" is any U.S. person that owns directly, indirectly or by attribution, 10% or more of the voting power of our outstanding shares. If we are classified as a CFC, a U.S. Shareholder may be subject to U.S. income taxation at ordinary income tax rates on all or a portion of our undistributed earnings and profits attributable to "subpart F income" and may also be subject to tax at ordinary income tax rates on any gain realized on a sale of ordinary shares, to the extent of our current and accumulated earnings and profits attributable to such shares. The CFC rules are complex and U.S. Shareholders of the ordinary shares are urged to consult their own tax advisors regarding the possible application of the CFC rules to them in their particular circumstances.

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Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our U.K. corporate headquarters and manufacturing facility are located in Abingdon, England. We presently lease 8,600 square feet of manufacturing, storage and mixed use space pursuant to a lease that extends through December 31, 2020, or possibly sooner. Our rent for this space is currently $24,500 per month. We also rent separate warehouse/storage space in Abingdon, England near our corporate headquarters. The lease on the warehouse/storage space expires in 2025, and our current rent is $67,000 annually, which is subject to change.

In June 2018, the Company entered into a lease for a new space in Abingdon, England, which extends through June 30, 2033, or the 143 Park Lease. The 143 Park Lease covers 27,000 square feet of laboratory, office, storage and other mixed use space and will allow us to combine our current manufacturing, laboratory, storage and office operations into a single facility. Initial rent under the 143 Park Lease is approximately $39,000 per month. When the leases on the Company's existing facilities have expired and it fully occupies the space subject to the 143 Park Lease, rent will increase to $79,000 per month. Rent will be reviewed for possible increases on June 1, 2021 and every third anniversary after that date.

Our U.S. corporate headquarters is located in Marlborough, Massachusetts. In August 2015, we entered into a lease amendment on this location to extend the term of the lease by two years through October 31, 2020. In addition, beginning in March 2016, the lease amendment expanded our office space at this location by 7,600 square feet to a new total of 22,100 square feet. The base rent for the combined space over the lease term will range from an initial low of $36,000 per month, which includes $12,000 per month for the expansion space commencing in early 2016, to a high of $39,000 per month. We will have an option to extend the lease for one additional term of five years. We also currently sublease approximately 9,000 square feet of warehousing and office space from Quest in Norwood, Massachusetts. The base rent for this space is approximately $17,000 per month. The sublease expires in November 2020.

Item 3. Legal Proceedings

On August 10, 2015, Oxford Immunotec Limited, a wholly-owned subsidiary of Oxford Immunotec Global PLC, filed suit in the United States District Court for the District of Massachusetts against Qiagen N.V., Qiagen Inc., Quest

Diagnostics LLC, and Laboratory Corporation of America Holdings alleging claims of patent infringement and seeking monetary and injunctive relief. The complaint alleged that the defendants' manufacture, sale and/or use of the QuantiFERON-TB Gold test infringes patents owned by Oxford Immunotec Limited.

On December 15, 2017, the Company reached a settlement in the lawsuit in the U.S. District Court for the District of Massachusetts in Boston (15-cv-13124-NMG) alleging patent infringement in relation to QIAGEN's QuantiFERON®-TB Gold and QuantiFERON®-TB Gold Plus products. Under terms of the agreement, all pending claims between the Company and QIAGEN and the co-defendants have been resolved. In connection with the settlement, the Company received a one-time, lump sum payment of $27.5 million from QIAGEN. As part of the settlement, the Company has granted QIAGEN a royalty-free, non-exclusive license that extends to all current and future customers of QuantiFERON-TB Gold and QuantiFERON-TB Gold Plus. The settlement includes general releases of all parties with no admissions of wrongdoing.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Market Information

Our ordinary shares trade on the NASDAQ Global Market under the symbol "OXFD." The price range per share reflected in the table below is the high and low sales prices of our ordinary shares as reported by NASDAQ (rounded to the nearest penny) for the periods presented.

	Year ended December 31, 2018		**Year ended December 31, 2017**	
	High	**Low**	**High**	**Low**
First quarter	$14.70	$10.00	$16.13	$12.96
Second quarter	14.90	12.11	16.90	13.53
Third quarter	19.19	11.66	19.51	14.35
Fourth quarter	17.11	11.88	17.20	12.19

Shareholders

On February 28, 2019, there were 10 shareholders of record of our ordinary shares. This number does not include shareholders for whom shares were held in a "nominee" or "street" name. On February 28, 2018, the last reported sale price per share of our ordinary shares on The NASDAQ Global Market was $16.69.

Dividends

We have never declared or paid cash dividends on our ordinary shares. We currently do not anticipate paying any cash dividends in the foreseeable future. Any future determination as to the declaration and payment of dividends, if any, will be made at the discretion of our Board of Directors and will depend on then existing conditions, including our results of operations, financial conditions, contractual restrictions, capital requirements, business prospects and other

factors our Board of Directors may deem relevant. Under English law, we may pay dividends only out of our accumulated, realized profits, so far as not previously utilized by distribution or capitalization, less our accumulated, realized losses, so far as not previously written off in a reduction or reorganization of capital duly made. Because we are a holding company and have no direct operations, we will only be able to pay dividends from our available cash on hand and any funds we receive from our subsidiaries.

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The following graph compares the cumulative total shareholder return on our ordinary shares with that of the NASDAQ Composite Index and the S&P Smallcap 600 Healthcare Index. The comparison assumes that $100.00 was invested at the close of market on November 22, 2013 in our ordinary shares or on October 31, 2013 in the NASDAQ Composite Index and the S&P Smallcap 600 Healthcare Index, and assumes reinvestment of dividends, if any. The performance graph is based on historical results and is not intended to suggest future performance.

This performance graph is being furnished pursuant to SEC rules and will not be incorporated by reference into any filing under the Securities Act or the Exchange Act except to the extent we specifically incorporate it by reference.

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Item 6. Selected Consolidated Financial Data

The following selected consolidated financial data for the five years ended December 31, 2018 are derived from our consolidated financial statements.

On October 2, 2013, we completed a scheme of arrangement under the laws of England and Wales, or the Scheme of Arrangement, which was approved by the High Court of Justice in England and Wales. Prior to the Scheme of Arrangement, our business was conducted by Oxford Immunotec Limited and its consolidated subsidiaries. Following the Scheme of Arrangement, our business has been conducted by Oxford Immunotec Global PLC and its consolidated subsidiaries, including Oxford Immunotec Limited.

On November 6, 2018, the Company completed an agreement to sell the Company's U.S. Laboratory Services Business. This agreement represents a strategic business shift having a major effect on the Company's operations and financial results. Therefore, in accordance with the accounting rules, the operations of this business have been reported in discontinued operations for all periods presented.

We have prepared the unaudited consolidated financial information presented below on the same basis as our audited consolidated financial statements. The unaudited consolidated financial information includes all adjustments, consisting only of normal recurring adjustments that are necessary for a fair presentation of our financial position and results of operations for these periods. Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the following selected financial data together with "Management's discussion and analysis of financial condition and results of operations" and our financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our financial statements and the accompanying notes.

	Year ended December 31,				
(in thousands, except share and per share data)	**2018[1]**	**2017[2]**	**2016**	**2015**	**2014**
Consolidated statement of operations data:					
Revenue	$59,753	$54,733	$46,988	$38,589	$31,967
Cost of revenue	16,826	18,470	16,491	14,508	7,848
Gross profit	42,927	36,263	30,497	24,081	24,119
Operating expenses:					
Research and development	8,122	10,835	9,370	7,106	5,560
Sales and marketing	26,500	29,053	26,858	23,242	20,219
General and administrative	25,952	25,450	18,918	14,041	13,665

Change in fair value of contingent purchase price consideration	—	(3,475)	(1,208)	202	72
Intangible assets impairment charges	879	18,300	1,765	419	—
Settlement expense	2,193	10,028	—	—	—
Total operating expenses	63,646	90,191	55,703	45,010	39,516
Operating loss from continuing operations	(20,719)	(53,928)	(25,206)	(20,929)	(15,397)
Other (expense) income	(4,062)	22,336	(146)	(156)	(159)
Loss from continuing operations before income taxes	(24,781)	(31,592)	(25,352)	(21,085)	(15,556)
Income tax benefit (expense) from continuing operations	37,286	(1,634)	3,774	(146)	(154)
Income (loss) from continuing operations	12,505	(33,226)	(21,578)	(21,231)	(15,710)
Discontinued operations:					
Income (loss) from discontinued operations before income taxes	1,727	341	(771)	(3,247)	(6,464)
Gain on disposition	145,982	—	—	—	—
Income tax expense	(39,435)	—	—	—	—
Income (loss) from discontinued operations	108,274	341	(771)	(3,247)	(6,464)
Net income (loss)	$120,779	$(32,885)	$(22,349)	$(24,478)	$(22,174)
Net income (loss) per ordinary share—basic					
Income (loss) from continuing operations	$0.48	$(1.40)	$(0.97)	$(0.97)	$(1.14)
Income (loss) from discontinued operations	4.17	0.01	(0.03)	(0.15)	(0.14)
Net income (loss)	$4.65	$(1.38)	$(1.00)	$(1.12)	$(1.28)
Net income (loss) per ordinary share—diluted					
Income (loss) from continuing operations	$0.47	$(1.40)	$(0.97)	$(0.97)	$(1.14)
Income (loss) from discontinued operations	4.10	0.01	(0.03)	(0.15)	(0.14)
Net income (loss)	$4.58	$(1.38)	$(1.00)	$(1.12)	$(1.28)
Weighted-average shares used to compute net income (loss) per ordinary share—basic	25,982,809	23,757,902	22,353,713	21,781,933	17,310,148
Weighted-average shares used to compute net income (loss) per ordinary share—diluted	26,397,875	23,757,902	22,353,713	21,781,933	17,310,148

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(1) Other income for 2018 includes a $146.0 million gain on the sale of our U.S. Laboratory Services Business to Quest pursuant to a Limited Liability Company Interest Purchase Agreement, from which we received net proceeds of approximately $130.2 million in cash. Upon closing of the Transaction, approximately $32.3 million was paid directly to MidCap Financial Trust, or MidCap, in settlement of all amounts due under our debt financing, which was comprised of both a term loan and a revolving line of credit. The payment to MidCap included prepayment and exit fees of approximately $2.3 million.

(2) Other income for 2017 includes a $27.5 million one-time, lump-sum payment for the settlement of a lawsuit. See Part I, Item 3. *Legal Proceedings* for further information.

	As of December 31,				
	2018	**2017**	**2016**	**2015**	**2014**
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$192,844	$90,332	$59,110	$83,715	$50,165
Total assets	232,120	144,236	124,012	109,852	73,849
Total liabilities	18,114	56,607	51,048	17,160	13,240
Total shareholders' equity	214,006	87,629	72,964	92,692	60,609
Ordinary shares outstanding	26,439,334	25,661,634	22,635,431	22,549,488	17,614,650

The following table presents a reconciliation of net loss, the most comparable U.S. GAAP measure, to EBITDA and Adjusted EBITDA for each of the periods indicated:

Reconciliation of net income (loss) to Adjusted EBITDA [(1)] (unaudited)

	Year Ended December 31,				
(in thousands)	**2018**	**2017**	**2016**	**2015**	**2014**
Reconciliation of net loss to adjusted EBITDA					
Net income (loss)	$120,779	$(32,885)	$(22,349)	$(24,478)	$(22,174)
Income (loss) from discontinued operations	108,274	341	(771)	(3,247)	(6,464)
Income (loss) from continuing operations	12,505	(33,226)	(21,578)	(21,231)	(15,710)
Income tax (benefit) expense	(37,286)	1,634	(3,774)	146	154
Interest expense, net	1,329	2,536	864	67	52
Loss on extinguishment of debt	2,105	—	—	—	—
Depreciation and amortization of intangible assets	1,662	1,618	932	1,294	1,036
Accretion and amortization of loan fees	468	569	—	—	—
EBITDA	(19,217)	(26,869)	(23,556)	(19,724)	(14,468)

Reconciling items:					
Share-based compensation expense	4,507	5,671	4,901	3,400	2,483
Unrealized exchange (gains) losses	(1,617)	686	(1,880)	(150)	(53)
Loss on change in fair value of warrants	—	—	—	—	22
Change in fair value of contingent purchase price consideration	—	(3,475)	(1,208)	202	72
Intangible assets impairment charges	879	18,300	1,765	419	—
Settlement expense	2,193	10,028	—	—	—
Litigation settlement income	—	(27,500)	—	—	—
Transaction expenses	3,333	—	—	—	—
Adjusted EBITDA	$(9,922)	$(23,159)	$(19,978)	$(15,853)	$(11,944)

(1) EBITDA and Adjusted EBITDA are non-GAAP measures that we calculate as net income (loss), adjusted for the impact of earnings or charges resulting from matters that we consider not to be indicative of our ongoing operations. We believe that these measures provide useful information to investors in understanding and evaluating our operating results in the same manner as our management and Board of Directors. Our presentation of these measures is not made in accordance with U.S. GAAP, and our computation of these measures may vary from others in the industry. Our use of these measures has limitations as an analytical tool, and you should not consider it in isolation or as a substitute for analysis of our results as reported under U.S. GAAP.

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

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes to those statements included elsewhere in this Annual Report on Form 10-K. In addition to our historical consolidated financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations. Our actual results and the timing of events could differ materially from those discussed in these forward-looking statements. Factors that could cause or contribute to these differences include those discussed below and elsewhere in this Annual Report on Form 10-K, particularly in Part I, Item 1A, "Risk Factors."

As previously disclosed, on September 25, 2018, Oxford Immunotec Global PLC (the "Company"), entered into a Limited Liability Company Interest Purchase Agreement (the "Purchase Agreement") with Quest Diagnostics Incorporated, a Delaware corporation ("Quest"), Oxford Immunotec Limited, a limited company incorporated in England and Wales and a wholly owned subsidiary of the Company ("Oxford Limited") and Oxford Immunotec, LLC, a Delaware limited liability company (formerly known as Oxford Immunotec, Inc., a Delaware corporation) and a wholly owned subsidiary of the Company ("Oxford LLC"), pursuant to which Oxford Limited agreed to sell, and Quest agreed to acquire, the Company's U.S. laboratory services business (the "U.S. Laboratory Services Business") for gross proceeds of $170 million in cash (the "Transaction"). Of this amount, approximately $32.3 million was paid directly to MidCap Financial Trust, or MidCap in settlement of all amounts due.

In conjunction with the Transaction, all prior year amounts in this Management's Discussion and Analysis of Financial Condition and Results of Operations have been recast to present our results, as if the Transaction had occurred prior to the earliest period presented. For more information on the Transaction, please see the below section entitled "Discontinued operations" and Note 19. Discontinued operations of our notes to consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K.

Overview

We are a global, high-growth diagnostics company focused on developing and commercializing proprietary tests for immunology and infectious disease by leveraging the technological, product development, manufacturing, quality, regulatory, and sales and marketing capabilities we have developed over our sixteen year history. Our proprietary T-SPOT.*TB* test utilizes our T-SPOT technology platform to test for tuberculosis, which is the leading cause of infectious disease death worldwide.

On November 6, 2018, we completed the sale of our U.S. Laboratory Services Business to Quest, for gross proceeds of $170 million in cash. This Transaction represented a strategic business shift and it had a major effect on our

operations and financial results. Following the Transaction, we have approximately 210 employees, including sales and marketing teams on three continents, and a laboratory in the United Kingdom.

Financial operations overview

Revenue

We generate revenue mainly from sales associated with our T-SPOT technology platform via our direct sales force and also through distributors. Our T-SPOT.*TB* test is our first commercialized product based on this technology.

We currently offer our T-SPOT.*TB* test as both an *in vitro* diagnostic kit and a service. In the former, we sell test kits and associated accessories to distributors for resale and directly to institutions and laboratories that perform TB testing. In the latter, we have an established clinical testing laboratory in the U.K., where we perform our T-SPOT.*TB* test on samples sent to us by customers. For the majority of our customers, we primarily negotiate pricing directly with our customers; our prices are influenced to some degree by the mechanism and level of funding our customers receive for performing tests for TB infection.

In conjunction with the Transaction, the parties entered into certain ancillary agreements as of the Closing Date, including: (i) a transitional services agreement, (ii) a technology license agreement and (iii) a long-term supply agreement, or the Supply Agreement, pursuant to which Oxford Immunotec USA, Inc., or Oxford USA, agreed to sell, and Quest agreed to purchase, T-SPOT.*TB* test kits and related accessories from Oxford USA. In addition, the parties entered into a strategic collaboration agreement to drive continued growth of T.SPOT.*TB* testing in the U.S.

Revenue by type

By type, total revenues were as summarized in the table below.

	Year ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
Revenue			
Product	$54,687	$48,899	$43,070
Service	5,066	5,834	3,918
Total revenue	$59,753	$54,733	$46,988

Revenue in the above table includes sales to the U.S. Laboratory Services Business, up to the date of the Transaction, at our intercompany transfer price that were formerly eliminated in consolidation.

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Revenue by geography

We have a direct sales force in the U.S., certain European countries and Japan and market development personnel in China and South Korea. In parts of the world where we do not maintain a direct sales force, we market and sell our products through distributors. As a result, our revenue is denominated in multiple currencies.

The following tables reflect revenue by geography (United States, Europe and rest of world, or Europe and ROW, and Asia) and as a percentage of total revenue, based on the billing address of our customers.

	Year ended December 31,					
(in thousands, except percentages)	**2018**		**2017**		**2016**	
Revenue						
United States	$16,442	28 %	$15,720	29 %	$10,372	22 %
Europe and ROW	9,153	15 %	8,136	15 %	6,988	15 %
Asia	34,158	57 %	30,877	56 %	29,628	63 %
Total revenue	$59,753	100%	$54,733	100%	$46,988	100%

Revenue in the above table includes sales to the U.S. Laboratory Services Business, up to the date of the Transaction, at our intercompany transfer price that were formerly eliminated in consolidation.

Cost of revenue and operating expenses

Cost of revenue and gross margin

Cost of revenue consists of direct labor expenses, including employee benefits and share-based compensation expenses, overhead expenses, material costs, cost of laboratory supplies, freight costs, royalties paid under license agreements, depreciation of laboratory equipment and leasehold improvements.

We expect our overall cost of revenue to increase as we continue to increase our volume of kits manufactured and tests performed. However, we also believe that through these increased volumes, we can achieve certain efficiencies in our manufacturing and laboratory operations that could help maintain or improve our overall margins.

On June 30, 2017, we entered into a Release and Settlement Agreement, or the Settlement Agreement, with Statens Serum Institut, or SSI, to resolve outstanding disputes arising from the license agreement with SSI. The terms of the Settlement Agreement are confidential. Based on the Settlement Agreement, we no longer expect to pay royalties to SSI, which has improved our margins. On December 19, 2017, the Company amended its license agreement with Rutgers, The State University of New Jersey, which reduced our royalties due under the license. This agreement has further improved our margins.

During the years ended December 31, 2018, 2017 and 2016, our cost of revenue represented 28%, 34% and 35%, respectively, of our total revenue.

	Year ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
Cost of revenue			
Product	$13,668	$13,864	$13,807
Service	3,158	4,606	2,684
Total cost of revenue	$16,826	$18,470	$16,491

Our gross profit represents total revenue less total cost of revenue, and gross margin is gross profit expressed as a percentage of total revenue. Our gross margins were 72%, 66% and 65%, respectively, for the years ended December 31, 2018, 2017 and 2016.

Research and development expenses

Our research and development efforts are focused on development programs to enhance our TB product offering. We are developing multiple product enhancements that aim to improve the clinical utility of our test and improve test workflow and automation.

Our research and development activities include performing research, development, clinical and regulatory activities and validating improvements to our technology and processes for the purposes of enhancing product performance. Research and development expenses include personnel-related expenses, including share-based compensation, fees for contractual and consulting services, clinical trial costs, travel costs, laboratory supplies, amortization, depreciation, rent, insurance and repairs and maintenance. We expense all research and development costs as incurred.

During the years ended December 31, 2018, 2017 and 2016, our research and development expenses represented 14%, 20% and 20%, respectively, of our total revenue.

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Sales and marketing expenses

Our sales and marketing expenses include costs associated with our sales organization, including our direct sales force and sales management, and our marketing, customer service and business development personnel. These expenses consist principally of salaries, commissions, bonuses and employee benefits for these personnel, including share-based compensation, as well as travel costs related to sales, marketing, customer service activities, medical education activities and overhead expenses. We expense all sales and marketing costs as incurred.

During the years ended December 31, 2018, 2017 and 2016, our sales and marketing expenses represented 44%, 53% and 57%, respectively, of our total revenue. The lower percentage in 2018 reflects lower headcount during the year.

General and administrative expenses

Our general and administrative expenses include costs for our executive, accounting, treasury, finance, legal, information technology, or IT, and human resources functions. These expenses consist principally of salaries, bonuses and employee benefits for the personnel included in these functions, including share-based compensation and travel costs, professional services fees, such as consulting, audit, tax and legal fees, costs related to our Board of Directors, general corporate costs, overhead expenses, and bad debt expense. Additionally, general and administrative expenses for 2018 include about $3.3 million of costs incurred as a result of the Transaction and a credit of $769,000 for income from the TSA agreement that was entered into in conjunction with the Transaction. We expense all general and administrative expenses as incurred.

During the years ended December 31, 2018, 2017 and 2016, our general and administrative expenses represented 43%, 46% and 40%, respectively, of our total revenue.

Change in fair value of contingent purchase price consideration

During March 2017, as a result of events subsequent to the acquisition of Immunetics, we determined that the timing for FDA approval of the *Babesia microti* product acquired as part of the acquisition would be more likely to occur after the cut-off date for a milestone to be paid. As a result, we recorded a $2.4 million decrease in fair value of contingent purchase price consideration related to the acquisition. The total contingent purchase price consideration of $6.0 million consisted of cash payable on the achievement of certain revenue thresholds and pipeline related milestones over the following three years, including FDA approval of the *Babesia microti* product by a certain date. The fair value of these milestone payments had been estimated to be $3.4 million on the date of acquisition based on

significant assumptions, including the probabilities of milestone occurrence, the expected timing of milestone payments, and a discount rate of 4.4%. As FDA approval did not occur in the second quarter of 2017, the remaining accrual related to this milestone of $238,000 was written-off. In the third quarter of 2017, we determined there to be a remote chance that the revenue thresholds for 2017 would be met and so the remaining contingent consideration liability of $880,000 was written-off.

During the fourth quarter of 2016, we made the strategic decision to end our GoutiFind program. GoutiFind was a blood test designed to allow for early diagnosis of gout and better inform therapies by measuring the strength of the underlying uric acid induced inflammation. As a result of this decision, we wrote-off the related liability for contingent purchase price consideration in connection with the acquisition of Boulder Diagnostics, Inc., or Boulder, in the amount of $901,000. During the same quarter, we determined that the SpiroFind assay developed using IPR&D from Boulder would not qualify for future milestone payments. Due to this fact, we wrote-off the related contingent purchase price consideration liability of $551,000.

Intangible assets impairment charges

During the fourth quarter of 2018, in conjunction with our change in focus following the Transaction, we determined that the intangible assets recorded in conjunction with the acquisition of Immunetics in the fourth quarter of 2016 had become impaired. Therefore, we recorded an impairment charge of $879,000 to write them off.

In the third quarter of 2017, due to increased competition in the molecular blood donor screening market for *Babesia microti*, we recorded an impairment charge of $11.1 million to write-off certain intangible assets acquired in conjunction with the 2016 acquisition of Imugen. Due to a mid-February CRL from FDA regarding the Company’s fourth quarter 2017 submissions in relation to its BLA application for the Immunetics *Babesia microti* blood donor screening assay, the Company recorded an impairment charge of $7.2 million to write-off the related intangible assets.

During the fourth quarter of 2016, in conjunction with the strategic decision to end our GoutiFind program, we recorded a non-cash IPR&D impairment charge of $270,000. Also during the fourth quarter of 2016, we recorded a non-cash in-process research and development, or IPR&D, impairment charge of $1.4 million related to the SpiroFind assay when it was determined that the Boulder IPR&D will not directly yield any products.

Settlement expense

Settlement expense for 2018 relates mainly to the June 18, 2018 Settlement Agreement with the former shareholders of Immunetics, or the Immunetics Settlement Agreement, to resolve disputes arising from the Agreement and Plan of Merger dated October 12, 2016. The terms of the Immunetics Settlement Agreement are confidential.

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Settlement expense for 2017 relates to the Settlement Agreement with SSI to resolve outstanding disputes arising from our previous license agreement. The terms of the SSI Settlement Agreement are confidential. Based on the SSI Settlement Agreement, we no longer pay royalties to SSI, which improves our margins.

Interest expense, net

Interest expense, net includes interest income on our available cash balances, which are in part invested in money market funds and repurchase agreements, primarily in U.S. government and agency securities, and bank savings accounts in the United States, United Kingdom, Germany, Japan, China and South Korea. Essentially all our cash is in the U.S. and the U.K. Interest expense mainly relates to our previous agreement with MidCap, or the MidCap agreement, that provided us with $40 million in debt financing, comprised of both a term loan and a revolving line of credit.

Loss on extinguishment of debt

Upon closing of the sale to Quest in the fourth quarter of 2018, approximately $32.3 million was paid directly to MidCap in settlement of all amounts due, which included prepayment and exit fees of $2.3 million and accrued interest of $67,000. This prepayment resulted in a loss on extinguishment of debt of $2.1 million, representing the cash paid to settle the debt in excess of debt related balances at the time of settlement.

Foreign exchange gains (losses)

Foreign exchange gains (losses) largely result from U.S. Dollar denominated bank accounts, accounts receivable, and accounts payable reflected on the books of Oxford Immunotec Limited, which has a functional currency of the U.K. Pound Sterling. We are exposed to foreign exchange rate risk because we currently operate in three major regions of the world: the United States, Europe and ROW, and Asia, and our revenue is denominated in multiple currencies. Sales in the United States, China and South Korea are denominated in U.S. Dollars. Sales in Europe are denominated primarily in the U.K. Pound Sterling and Euro. As we grow Europe and ROW sales outside the United Kingdom and the Euro Zone, we may be subject to risk from additional currencies. Sales in Japan are denominated in Yen.

Other income (expense)

Other income (expense) includes foreign exchange gains/ (losses) and other income and expense items. In addition, in December 2017, the Company reached a settlement in a lawsuit in exchange for a one-time, lump-sum receipt of $27.5 million. The settlement included general releases of all parties with no admissions of wrongdoing.

Monetary assets and liabilities that are denominated in foreign currencies are remeasured at the period-end closing rate with resulting unrealized exchange fluctuations. Realized exchange fluctuations result from the settlement of transactions in currencies other than the functional currencies of our businesses. The functional currencies of our businesses are U.S. Dollars, Pounds Sterling, Euros, Japanese Yen and Chinese Yuan, depending on the entity.

Income (loss) from discontinued operations

On November 6, 2018, we completed an agreement to sell our U.S. Laboratory Services Business to Quest. This agreement represents a strategic business shift having a major effect on our operations and financial results. Accordingly, the operations of this business have been reported in discontinued operations in the consolidated financial statements for all periods presented. Income from discontinued operations for 2018 of $108.3 million includes a $146.0 million gain on the sale.

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Results of operations

Comparison of years ended December 31, 2018 and 2017

The following table sets forth, for the periods indicated, the amounts of certain components of our statements of operations and the percentage of total revenue represented by these items, showing period-to-period changes.

	Year ended December 31,								
	2018			2017			Change		
(in thousands, except percentages)	**Amount**	**% of revenue**		**Amount**	**% of revenue**		**Amount**	**%**	
Revenue:									
Product	$54,687	92	%	$48,899	89	%	$5,788	12	%
Service	5,066	8	%	5,834	11	%	(768)	(13)	%
Total revenue	59,753	100	%	54,733	100	%	5,020	9	%
Cost of revenue:									
Product	13,668	23	%	13,864	25	%	(196)	(1)	%
Service	3,158	5	%	4,606	8	%	(1,448)	(31)	%
Total cost of revenue	16,826	28	%	18,470	34	%	(1,644)	(9)	%
Gross profit	42,927	72	%	36,263	66	%	6,664	18	%
Operating expenses:									
Research and development	8,122	13	%	10,835	20	%	(2,713)	(25)	%
Sales and marketing	26,500	44	%	29,053	53	%	(2,553)	(9)	%
General and administrative	25,952	43	%	25,450	46	%	502	2	%
Change in fair value of contingent purchase price consideration	—	—	%	(3,475)	(6)	%	3,475	(100)	%
Intangible assets impairment charge	879	1	%	18,300	33	%	(17,421)	(95)	%
Settlement expense	2,193	4	%	10,028	18	%	(7,835)	(78)	%
Total operating expenses	63,646	107	%	90,191	165	%	(26,545)	(29)	%
Operating loss from continuing operations	(20,719)	(34)	%	(53,928)	(99)	%	33,209	(62)	%
Interest expense, net	(1,797)	(3)	%	(3,105)	(6)	%	1,308	(42)	%
Loss on extinguishment of debt	(2,105)	(4)	%	—	—	%	(2,105)	N/M	
Foreign exchange gains (losses)	111	0	%	(1,850)	(3)	%	1,961	(106)	%
Other expense	(271)	(0)	%	(209)	(0)	%	(62)	30	%
Litigation settlement income	—	—	%	27,500	50	%	(27,500)	(100)	%
Loss from continuing operations before income taxes	(24,781)	(41)	%	(31,592)	(58)	%	6,811	(22)	%

Income tax benefit (expense) from continuing operations	37,286	62	%	(1,634)	(3	)%	38,920	N/M
Income (loss) from continuing operations	12,505	21	%	(33,226)	(61	)%	45,731	N/M
Discontinued operations:								
Income from discontinued operations before income taxes	1,727	3	%	341	1	%	1,386	406 %
Gain on disposition	145,982	244	%	—	—	%	145,982	N/M
Income tax expense	(39,435)	(66	)%	—	—	%	(39,435)	N/M
Income from discontinued operations	108,274	181	%	341	1	%	107,933	N/M
Net income (loss)	$120,779	202	%	$(32,885)	(60	)%	$153,664	N/M

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Revenue

Revenue increased by 9% to $59.8 million for the year ended December 31, 2018 compared to $54.7 million for the same period in 2017.

U.S. revenue, excluding revenue from discontinued operations, increased by 5%, to $16.4 million for the year ended December 31, 2018, compared to $15.7 million for the same period in 2017.

Asia revenue, including revenue from our sales office in South Korea that opened in 2017, increased by 11%, to $34.2 million, compared to the same period in 2017, due primarily to the timing of shipments to China. On a non-Generally Accepted Accounting Principles, or non-GAAP, constant currency basis, revenue for Asia would have increased by 10%. Europe and ROW revenue increased by 13% to $9.2 million, compared to the same period in 2017. On a non-GAAP constant currency basis, Europe and ROW revenue would have increased by 8% in 2018 compared to 2017.

Changes in revenue include the impact of changes in foreign currency exchange rates. We use the non-GAAP financial measure “constant currency basis” in our filings to show changes in our revenue without giving effect to period-to-period currency fluctuations. Under U.S. GAAP, revenues received in local (non-U.S. Dollar) currencies are translated into U.S. Dollars at the average exchange rate for the period presented. When we use the term “constant currency basis”, it means that we have translated local currency revenues for the prior reporting period into U.S. Dollars using the same average foreign currency exchange rates for the conversion of revenues into U.S. Dollars that we used to translate local currency revenues for the comparable reporting period of the current year. We then calculate the change, as a percentage, from the prior period revenues using the current period exchange rates versus the current period revenues. This resulting percentage is a non-GAAP measure referring to a change as a percentage on a “constant currency basis”. We consider the use of a period over period revenue comparison on a constant currency basis to be helpful to investors, as it provides a revenue growth measure free of positive or negative volatility due to currency fluctuations.

By revenue type, total revenues were:

	Year ended December 31,		Change	
(in thousands, except percentages)	**2018**	**2017**	**Amount**	**%**
Revenue				
Product	$54,687	$48,899	$5,788	12 %
Service	5,066	5,834	(768)	(13)%

Total revenue	$59,753	$54,733	$5,020	9 %

Revenue in the above table includes sales to the U.S. Laboratory Services Business, up to the date of the Transaction, at our intercompany transfer price that were formerly eliminated in consolidation. Overall growth reflects increased TB sales. The decline in service revenue was due to our withdrawal from the Babesia testing market.

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By geography, total revenues were:

(in thousands, except percentages)	Year ended December 31, 2018	2017	Change Amount	%
Revenue				
United States	$16,442	$15,720	$722	5 %
Europe and ROW	9,153	8,136	1,017	13%
Asia	34,158	30,877	3,281	11%
Total revenue	$59,753	$54,733	$5,020	9 %

Revenue in the above table includes sales to the U.S. Laboratory Services Business, up to the date of the Transaction, at our intercompany transfer price that were formerly eliminated in consolidation.

Cost of revenue and gross margin

Cost of revenue decreased by 9% to $16.8 million for the year ended December 31, 2018 from $18.5 million in the same period in 2017. Gross margin for 2018 increased to 72% from 66% for 2017. The increase in gross margin reflects the impact of improved accessory margins and lower royalty expense due to the Settlement Agreement with SSI and the license agreement with Rutgers that was amended in December 2017.

(in thousands, except percentages)	Year ended December 31, 2018	2017	Change Amount	%
Cost of revenue				
Product	$13,668	$13,864	$(196)	(1)%
Service	3,158	4,606	(1,448)	(31)%
Total cost of revenue	$16,826	$18,470	$(1,644)	(9)%

Research and development expenses

Research and development expenses decreased to $8.1 million for the year ended December 31, 2018 from $10.8 million for the same period in 2017. The decrease was largely due to lower clinical costs and consulting costs. Additionally, costs in 2017 were higher due to our efforts related to BLAs for three *Babesia microti* blood donor

screening assays. Our efforts in this area ended in early 2018 following receipt of two BLA approvals for Imugen assays in March 2018 (Arrayed Fluorescence Immunoassay and Nucleic acid Amplification Test), and receipt of a CRL from FDA for our Immunetics BLA in February 2018, which raised a number of questions related to our submissions in the fourth quarter of 2017 in support of licensure. As a percentage of total revenue, research and development expenses declined to 13% for the year ended December 31, 2018 compared to 20% for the same period in 2017.

Sales and marketing expenses

Sales and marketing expenses decreased to $26.5 million for the year ended December 31, 2018 from $29.1 million for the same period in 2017. The decrease was largely due to lower salary and other employee related expenses and a decrease in marketing costs. As a percentage of total revenue, sales and marketing expenses declined to 44% for the year ended December 31, 2018 compared to 53% for the same period in 2017.

General and administrative expenses

General and administrative expenses increased to $26.0 million for the year ended December 31, 2018 from $25.5 million for the same period in 2017. The increase in general and administrative expenses largely reflected $3.3 million of costs incurred as a result of the Transaction for the year ended December 31, 2018. This increase was partially offset by a decrease in legal fees for a patent infringement action against Qiagen that was settled in December 2017. Legal fees of $5.1 million were incurred for this action in 2017 and declined to $1.8 million in 2018.

Change in fair value of contingent purchase price consideration

During March 2017, as a result of events subsequent to the acquisition of Immunetics, we determined that the timing for FDA approval of the *Babesia microti* product acquired as part of the acquisition would be more likely to occur after the cut-off date for a milestone to be paid. As a result, we recorded a $2.4 million decrease in fair value of contingent purchase price consideration related to the acquisition. The total contingent purchase price consideration of $6.0 million consisted of cash payable on the achievement of certain revenue thresholds and pipeline related milestones over the following three years, including FDA approval of the *Babesia microti* product by a certain date. The fair value of these milestone payments had been estimated to be $3.4 million on the date of acquisition based on significant assumptions, including the probabilities of milestone occurrence, the expected timing of milestone payments, and a discount rate of 4.4%. As FDA approval did not occur in the second quarter of 2017, the remaining accrual related to this milestone of $238,000 was written-off at that time. In the third quarter of 2017, we determined there to be a remote chance that the revenue thresholds for 2017 would be met and so the remaining contingent consideration liability of $880,000 was written-off.

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Intangible assets impairment charges

During the fourth quarter of 2018, in conjunction with our change in focus following the Transaction, we determined that the intangible assets recorded in conjunction with the acquisition of Immunetics in the fourth quarter of 2016 had become impaired. Therefore, we recorded an impairment charge of $879,000 to write them off.

In the third quarter of 2017, due to increased competition in the molecular blood donor screening market for *Babesia microti*, we recorded an impairment charge of $11.1 million to write-off certain intangible assets acquired in conjunction with the 2016 acquisition of Imugen. Due to a mid-February CRL from FDA regarding the Company's fourth quarter 2017 submissions in relation to its BLA for the Immunetics *Babesia microti* blood donor screening assay, the Company recorded an impairment charge of $7.2 million to write-off the related intangible assets.

Settlement expense

Settlement expense for 2018 relates mainly to the Immunetics Settlement Agreement. The terms of the Immunetics Settlement Agreement are confidential. Settlement expense for 2017 relates to the SSI Settlement Agreement. The terms of the SSI Settlement Agreement are confidential.

Interest expense, net

Interest expense, net was $1.8 million for the year ended December 31, 2018, compared to $3.1 million in the same period in 2017. Interest expense, net consists of our previous MidCap agreement that provided us with $40 million in debt financing, comprised of both a term loan and a revolving line of credit, offset by interest income received on our short-term investments.

Loss on extinguishment of debt

Upon closing of the sale to Quest in the fourth quarter of 2018, approximately $32.3 million was paid directly to MidCap in settlement of all amounts due, which included prepayment and exit fees of $2.3 million and accrued interest of $67,000. This prepayment resulted in a loss on extinguishment of debt of $2.1 million, representing the cash paid to settle the debt in excess of debt related balances at the time of settlement.

Foreign exchange (losses) gains

We recorded foreign exchange gains of $111,000 for the year ended December 31, 2018, substantially all as a net result of U.S. Dollar denominated bank accounts, accounts receivable, and accounts payable reflected on the books of Oxford Immunotec Limited, which has a functional currency of the U.K. Pound Sterling. For the year ended December 31, 2017, we recorded foreign exchange losses of $1.9 million. We are exposed to foreign exchange rate risk because we currently operate in three major regions of the world: the United States, Europe and ROW, and Asia, and our revenue is denominated in multiple currencies. Approximately 29% of our sales for the year ended December 31, 2018 were in the United States, which are denominated in U.S. Dollars. Sales in China and South Korea are also denominated in U.S. Dollars. Sales in Europe are denominated primarily in the U.K. Pound Sterling and the Euro. As we grow Europe and ROW sales outside the United Kingdom and the Euro Zone, we may be subject to risk from additional currencies. Sales in Japan are denominated in Yen.

Our expenses are generally denominated in the currencies in which our operations are located, which are primarily in the United States, the United Kingdom, Japan, Europe, China and South Korea. As we continue to grow our business outside the United States, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any foreign currency hedging contracts, although we may do so in the future.

Other expense

Other expense was $271,000 for the year ended December 31, 2018, compared to $209,000 in the same period in 2017.

Litigation settlement income

In December 2017, the Company reached a settlement in a lawsuit in exchange for a one-time, lump-sum receipt of $27.5 million. The settlement included general releases of all parties with no admissions of wrongdoing.

Income (loss) from discontinued operations

Discontinued operations represent the U.S. Laboratory Services Business that we sold to Quest on November 6, 2018. For financial statement purposes, the net assets and results of operations for the discontinued operations have been

segregated from those of our continuing operations for all periods presented and are presented in our consolidated financial statements as discontinued operations.

There was income from discontinued operations of $108.3 million for the year ended December 31, 2018, which included a gain on disposition of $146.0 million, compared to income from discontinued operations for the year ended December 31, 2017 of $341,000.

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Comparison of years ended December 31, 2017 and 2016

The following table sets forth, for the periods indicated, the amounts of certain components of our statements of operations and the percentage of total revenue represented by these items, showing period-to-period changes.

	Year ended December 31,								
	2017			2016			Change		
(in thousands, except percentages)	**Amount**	**% of revenue**		**Amount**	**% of revenue**		**Amount**	**%**	
Revenue:									
Product	$48,899	89	%	$43,070	92	%	$5,829	14	%
Service	5,834	11	%	3,918	8	%	1,916	49	%
Total revenue	54,733	100	%	46,988	100	%	7,745	16	%
Cost of revenue:									
Product	13,864	25	%	13,807	29	%	57	0	%
Service	4,606	8	%	2,684	6	%	1,922	72	%
Total cost of revenue	18,470	34	%	16,491	35	%	1,979	12	%
Gross profit	36,263	66	%	30,497	65	%	5,766	19	%
Operating expenses:									
Research and development	10,835	20	%	9,370	20	%	1,465	16	%
Sales and marketing	29,053	53	%	26,858	57	%	2,195	8	%
General and administrative	25,450	46	%	18,918	40	%	6,532	35	%
Change in fair value of contingent purchase price consideration	(3,475)	(6	)%	(1,208)	(3	)%	(2,267)	188	%
Intangible assets impairment charges	18,300	33	%	1,765	4	%	16,535	937	%
Settlement expense	10,028	18	%	—	0	%	10,028	N/M	
Total operating expenses	90,191	165	%	55,703	119	%	34,488	62	%
Operating loss from continuing operations	(53,928)	(99	)%	(25,206)	(54	)%	(28,722)	114	%
Interest expense, net	(3,105)	(6	)%	(864)	(2	)%	(2,241)	259	%
Foreign exchange (losses) gains	(1,850)	(3	)%	1,364	3	%	(3,214)	(236	)%
Other expense	(209)	(0	)%	(646)	(1	)%	437	(68	)%
Litigation settlement income	27,500	50	%	—	0	%	27,500	N/M	
Loss from continuing operations before income taxes	(31,592)	(58	)%	(25,352)	(54	)%	(6,240)	25	%
Income tax (expense) benefit from continuing operations	(1,634)	(3	)%	3,774	8	%	(5,408)	(143	)%
Loss from continuing operations	(33,226)	(61	)%	(21,578)	(46	)%	(11,648)	54	%
Discontinued operations:									
	341	1	%	(771)	(2	)%	1,112	144	%

Income (loss) from discontinued operations before income taxes									
Income tax expense	—	—	%	—	—	%	—	—	%
Income (loss) from discontinued operations	341	1	%	(771)	(2)%		1,112	144	%
Net loss	$(32,885)	(60)%		$(22,349)	(48)%		$(10,536)	47	%

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Revenue

Revenue increased by 16% to $54.7 million for the year ended December 31, 2017 compared to $47.0 million for the same period in 2016. This increase in revenue was mainly due to an increase in volumes across all regions where we sell our T-SPOT.*TB* test.

U.S. revenue grew by 52%, to $15.7 million for the year ended December 31, 2017, compared to $10.4 million for the same period in 2016.

Asia revenue, including revenue from our sales office in South Korea that opened in 2017, grew by 4%, to $30.9 million, compared to the same period in 2016, due primarily to an increase in volumes that led to higher revenue. On a non-Generally Accepted Accounting Principles, or non-GAAP, constant currency basis, revenue for Asia would have increased by 6%. Europe and ROW revenue increased by 16% to $8.1 million, compared to the same period in 2016. On a non-GAAP constant currency basis, Europe and ROW revenue would have increased by 17% in 2017 compared to 2016.

Changes in revenue include the impact of changes in foreign currency exchange rates. We use the non-GAAP financial measure “constant currency basis” in our filings to show changes in our revenue without giving effect to period-to-period currency fluctuations. Under U.S. GAAP, revenues received in local (non-U.S. Dollar) currencies are translated into U.S. Dollars at the average exchange rate for the period presented. When we use the term “constant currency basis”, it means that we have translated local currency revenues for the prior reporting period into U.S. Dollars using the same average foreign currency exchange rates for the conversion of revenues into U.S. Dollars that we used to translate local currency revenues for the comparable reporting period of the current year. We then calculate the change, as a percentage, from the prior period revenues using the current period exchange rates versus the current period revenues. This resulting percentage is a non-GAAP measure referring to a change as a percentage on a “constant currency basis”. We consider the use of a period over period revenue comparison on a constant currency basis to be helpful to investors, as it provides a revenue growth measure free of positive or negative volatility due to currency fluctuations.

By revenue type, total revenues were:

	Year ended December 31,		Change	
(in thousands, except percentages)	**2017**	**2016**	**Amount**	**%**
Revenue				
Product	$48,899	$43,070	$5,829	14%
Service	5,834	3,918	1,916	49%

Total revenue	$54,733	$46,988	$7,745	16%

Revenue in the above table includes sales to the U.S. Laboratory Services Business, up to the date of the Transaction, at our intercompany transfer price that were formerly eliminated in consolidation.

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By geography, total revenues were:

(in thousands, except percentages)	Year ended December 31, 2017	2016	Change Amount	%
Revenue				
United States	$15,720	$10,372	$5,348	52%
Europe and ROW	8,136	6,988	1,148	16%
Asia	30,877	29,628	1,249	4 %
Total revenue	$54,733	$46,988	$7,745	16%

United States revenue in the above table includes sales to the U.S. Laboratory Services Business, up to the date of the Transaction, at our intercompany transfer price that were formerly eliminated in consolidation.

Cost of revenue and gross margin

Cost of revenue increased by 12% to $18.5 million for the year ended December 31, 2017 from $16.5 million in the same period in 2016. Gross margin for 2017 increased to 66% from 65% for 2016. The increase in gross margin reflects lower royalty expense due to the Settlement Agreement with SSI and the license agreement with Rutgers that was amended in December 2017.

(in thousands, except percentages)	Year ended December 31, 2017	2016	Change Amount	%
Cost of revenue				
Product	$13,864	$13,807	$57	0 %
Service	4,606	2,684	1,922	72%
Total cost of revenue	$18,470	$16,491	$1,979	12%

Research and development expenses

Research and development expenses increased by 16% to $10.8 million for the year ended December 31, 2017 from $9.4 million for the same period in 2016. As a percentage of total revenue, research and development expenses remained relatively constant at 20% for each of the periods ended December 31, 2017 and 2016.

Sales and marketing expenses

Sales and marketing expenses increased 8% to $29.1 million for the year ended December 31, 2017 from $26.9 million for the same period in 2016. As a percentage of total revenue, sales and marketing expenses decreased to 53% for the year ended December 31, 2017 from 57% for the same period in 2016.

General and administrative expenses

General and administrative expenses increased by 35% to $25.5 million for the year ended December 31, 2017 from $18.9 million for the same period in 2016. The increase in general and administrative expenses included increases in legal and professional fees, largely related to patent litigation. As a percentage of total revenue, general and administrative expenses increased to 46% for the year ended December 31, 2017 from 40% for the same period in 2016.

Change in fair value of contingent purchase price consideration

During March 2017, as a result of events subsequent to the acquisition of Immunetics, we determined that the timing for FDA approval of the *Babesia microti* product acquired as part of the acquisition would be more likely to occur after the cut-off date for a milestone to be paid. As a result, we recorded a $2.4 million decrease in fair value of contingent purchase price consideration related to the acquisition. The total contingent purchase price consideration of $6.0 million consisted of cash payable on the achievement of certain revenue thresholds and pipeline related milestones over the following three years, including FDA approval of the *Babesia microti* product by a certain date. The fair value of these milestone payments had been estimated to be $3.4 million on the date of acquisition based on significant assumptions, including the probabilities of milestone occurrence, the expected timing of milestone payments, and a discount rate of 4.4%. As FDA approval did not occur in the second quarter of 2017, the remaining accrual related to this milestone of $238,000 was written-off at that time. In the third quarter of 2017, we determined there to be a remote chance that the revenue thresholds for 2017 would be met and so the remaining contingent consideration liability of $880,000 was written-off.

During the fourth quarter of 2016, we made the strategic decision to end our GoutiFind program. GoutiFind was a blood test designed to allow for early diagnosis of gout and to better inform therapies by measuring the strength of underlying uric acid induced inflammation. As a result of this decision, we wrote-off the related liability for contingent purchase price consideration in connection with the Boulder acquisition in the amount of $901,000. During the same quarter, we determined that the SpiroFind assay developed using IPR&D from Boulder would not qualify for future milestone payments. Due to this fact, we wrote-off the related liability for contingent purchase price consideration of $551,000. The combined credit of $1.5 million was partially offset by a charge of $244,000 related to the change in the fair value of contingent purchase price consideration related to the Boulder and Immunetics acquisitions.

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Intangible assets impairment charges

In the third quarter of 2017, due to increased competition in the molecular blood donor screening market for *Babesia microti*, we recorded an impairment charge of $11.1 million to write-off certain intangible assets acquired in conjunction with the 2016 acquisition of Imugen. Due to a mid-February CRL from FDA regarding the Company's fourth quarter 2017 submissions in relation to its BLA for the Immunetics *Babesia microti* blood donor screening assay, the Company recorded an impairment charge of $7.2 million to write-off the related intangible assets.

During the fourth quarter of 2016, in conjunction with the strategic decision to end our GoutiFind program, we recorded a non-cash IPR&D impairment charge of $270,000. Also during the fourth quarter of 2016, we recorded a non-cash IPR&D impairment charge of $1.4 million related to the SpiroFind assay when it was determined that the Boulder IPR&D would not directly yield any products.

Settlement expense

Settlement expense for the year ended December 31, 2017 related to the Settlement Agreement with SSI to resolve outstanding disputes arising from our previous license agreement. The terms of the Settlement Agreement are confidential.

Interest expense, net

Interest expense, net was $3.1 million for the year ended December 31, 2017, compared to $864,000 in the same period in 2016. The increase in interest expense in 2017 mainly related to the Midcap agreement that provided us with $40 million in debt financing, comprised of both a term loan and a revolving line of credit. The MidCap agreement provided a term loan of $30 million, which was to mature five years from closing. The term loan accrued interest at a rate of LIBOR plus 7.60% with interest only payments for the first 24 months, with the ability to extend to 48 months subject to certain conditions, before the loan was to begin to amortize. The MidCap agreement also provided a revolving line of credit of up to $10 million, which was to mature five years from closing. The revolving line of credit accrued interest at a rate of LIBOR plus 4.45%. Based on certain conditions, both the term loan and revolving line of credit could have been increased by an additional $10 million for a total of $60 million. We never borrowed under the revolving line of credit.

Foreign exchange (losses) gains

We recorded foreign exchange losses of $1.9 million for the year ended December 31, 2017, substantially all as a net result of U.S. Dollar denominated bank accounts, accounts receivable and accounts payable reflected on the books of Oxford Immunotec Limited, which has a functional currency of the U.K. Pound Sterling. For the year ended December 31, 2016, we recorded foreign exchange gains of $1.4 million. We have been exposed to foreign exchange rate risk because we operate in three major regions of the world: the United States, Europe and ROW and Asia, and our revenue is denominated in multiple currencies. Approximately 28% of our sales for 2017 were in the United States, which are denominated in U.S. Dollars. Sales in China and South Korea are also denominated in U.S. Dollars. Sales in Europe are denominated primarily in the U.K. Pound Sterling and the Euro. As we grow Europe and ROW sales outside the United Kingdom and the Euro Zone, we may be subject to risk from additional currencies. Sales in Japan are denominated in Yen.

Our expenses are generally denominated in the currencies in which our operations are located, which are primarily in the United States, the United Kingdom, Japan, Europe, China and South Korea. As we continue to grow our business outside the United States, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any foreign currency hedging contracts, although we may do so in the future.

Other expense

Other expense was $209,000 for the year ended December 31, 2017, compared to $646,000 in the same period in 2016, which included a fixed asset impairment charge of $306,000.

Litigation settlement income

In December 2017, the Company reached a settlement in a lawsuit in exchange for a one-time, lump-sum receipt of $27.5 million. The settlement included general releases of all parties with no admissions of wrongdoing.

Income (loss) from discontinued operations

Discontinued operations represent the U.S. Laboratory Services Business that we sold to Quest on November 6, 2018. For financial statement purposes, results of operations for the discontinued operations have been segregated from those of our continuing operations and are presented in our consolidated financial statements as discontinued operations.

There was income from discontinued operations of $341,000 for the year ended December 31, 2017, compared to a loss from discontinued operations for the year ended December 31, 2016 of $771,000.

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Liquidity and capital resources

Sources of funds

Since our inception, we have incurred significant net losses and negative cash flows from operations. However, for the year ended December 31, 2018 we had income from continuing operations of $12.5 million, largely relating to a tax benefit recorded in conjunction with the Transaction, while using $32.1 million of cash for operating activities. As of December 31, 2018, we had an accumulated deficit of $80.8 million. We incurred a loss from continuing operations of $33.2 million and used $13.1 million of cash for operating activities from continuing operations for the year ended December 31, 2017.

On November 6, 2018, we completed the sale of our U.S. Laboratory Services Business to Quest, for gross proceeds of $170 million in cash. We received net proceeds of approximately $130.2 million in cash. In conjunction with the closing of the Transaction, approximately $32.3 million was paid directly to MidCap in settlement of all amounts due under our debt financing, which was comprised of both a term loan and a revolving line of credit. The payment to MidCap included prepayment and exit fees of approximately $2.3 million.

On August 14, 2017, we entered into an underwriting agreement, or the Underwriting Agreement, with BTIG, LLC, as sole underwriter, or the Underwriter, relating to the issuance and sale of 2,500,000 ordinary shares, nominal value £0.006705 per share, or the Ordinary Shares, at a price to the public of $16.05 per share, or the Offering, which resulted in approximately $39.3 million of net proceeds to us after deducting underwriting discounts and estimated offering expenses. The Offering closed on August 18, 2017.

As of December 31, 2018, we had cash and cash equivalents of $192.8 million. We maintain our available cash balances in cash, money market funds and repurchase agreements primarily invested in U.S. government and agency securities, and bank savings accounts in the United States, United Kingdom, Germany, Japan, China and South Korea. Essentially all our cash is in the U.S. and the U.K.

Settlement agreement

Settlement expense for 2018 relates mainly to Immunetics Settlement Agreement. The terms of the Immunetics Settlement Agreement are confidential. Settlement expense for 2017 relates to the Settlement Agreement with SSI to resolve outstanding disputes arising from our previous license agreement. The terms of the SSI Settlement Agreement are confidential. Based on the SSI Settlement Agreement, we no longer pay royalties to SSI.

Summary of cash flows

The following table summarizes our cash and cash equivalents, accounts receivable and cash flows for the periods indicated:

	As of and for the years ended	
(in thousands)	**December 31, 2018**	**2017**
Cash and cash equivalents, including restricted cash	$ 192,944	$ 90,532
Accounts receivable, net	9,158	6,021
Net cash used in operating activities from continuing operations	$ (32,119)	$ (13,122)
Net cash used in investing activities from continuing operations	(5,350)	(1,295)
Net cash (used in) provided by financing activities	(29,307)	39,386
Net operating cash flows provided by discontinued operations	14,729	9,548
Net investing cash flows provided by (used in) discontinued operations	156,218	(3,734)
Net financing cash flows used in discontinued operations	(48)	(12)
Effect of exchange rate changes on cash and cash equivalents, including restricted cash	(1,711)	451

Net increase in cash and cash equivalents, including restricted cash	$	102,412	$	31,222

Cash flows for the years ended December 31, 2018 and 2017

Operating activities from continuing operations

Net cash used in operating activities from continuing operations was $32.1 million during the year ended December 31, 2018, which included net income of $12.5 million, a net credit from non-cash items of $29.2 million, and cash used for changes in operating assets and liabilities of $15.4 million. The non-cash items included a credit related to deferred income taxes of $38.8 million, partially offset by share-based compensation expense of $4.5 million, accretion and amortization of loan fees of $2.4 million, depreciation and amortization of intangible assets of $1.7 million, an intangible assets impairment charge of $879,000, and a loss on disposal of property and equipment of $115,000. The cash used for changes in operating assets and liabilities included a decrease in accounts payable and accrued liabilities of $7.1 million, a decrease in other liabilities of $4.2 million, an increase in accounts receivable of $3.4 million, and an increase in inventory of $1.0 million, partially offset by a decrease in prepaid expenses and other assets of $207,000. The decrease in accounts payable and accrued liabilities was largely due to payments in 2018 for royalties on intellectual property and bonuses that were accrued for at December 31, 2017, as well as the timing of payments. The decrease in other liabilities reflects the timing of payments. The increase in accounts receivable reflects the timing of customer payments. The increase in inventory was due to timing. The decrease in prepaid expenses and other assets reflects the timing of certain payments.

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Net cash used in operating activities from continuing operations was $13.1 million during the year ended December 31, 2017, which included a net loss of $33.2 million, net non-cash expenses of $24.6 million and cash used in changes in operating assets and liabilities of $4.5 million. The non-cash items consisted of intangible assets impairments charges of $18.3 million, share-based compensation expense of $5.7 million, depreciation and amortization expense of $1.6 million, a decrease in deferred tax assets of $1.6 million, accretion and amortization of loan fees expense of $569,000, and a $298,000 loss on disposal of property and equipment. Partially offsetting these charges was a credit for the change in fair value of contingent purchase price consideration of $3.5 million. The cash used in operating assets and liabilities included a decrease in accounts payable and accrued liabilities of $5.0 million, an increase in inventory of $1.8 million and an increase in accounts receivable of $988,000 million, partially offset by an increase in other liabilities of $3.7 million. The decrease in accounts payable and accrued liabilities reflects the timing of certain payments. Inventory increased due to timing. The increase in accounts receivable reflects growing sales. The increase in other liabilities is mainly due to the long-term portion of the settlement with SSI.

Investing activities from continuing operations

Net cash used in investing activities from continuing operations was $5.4 million during the year ended December 31, 2018 and consisted of purchases of property and equipment.

Net cash used in investing activities from continuing operations was $1.3 million during the year ended December 31, 2017 and consisted of purchases of property and equipment.

Financing activities from continuing operations

Net cash used in financing activities was $29.3 million during the year ended December 31, 2018 and consisted of $30.0 million to pay off the debt to MidCap, $2.1 million for a loss on extinguishment of debt, and payments of $383,000 for tax withheld on vesting of restricted share units, partially offset by $3.2 million in proceeds from the exercise of share options.

Net cash provided by financing activities was $39.4 million during the year ended December 31, 2017, which mainly reflected an offering that closed on August 18, 2017 and which resulted in approximately $39.3 million of net proceeds to us after deducting underwriting discounts and offering expenses.

Discontinued operations

Net cash provided by discontinued operations for 2018 was $170.9 million, primarily due to the gain on disposition from the sale of the U.S. Laboratory Services Business to Quest, compared to $5.8 million for 2017.

Cash flows for the years ended December 31, 2017 and 2016

Operating activities from continuing operations

Net cash used in operating activities from continuing operations was $13.1 million during the year ended December 31, 2017, which included a net loss of $33.2 million, net non-cash expenses of $24.6 million and cash used in changes in operating assets and liabilities of $4.5 million. The non-cash items consisted of intangible assets impairments charges of $18.3 million, share-based compensation expense of $5.7 million, depreciation and amortization expense of $1.6 million, a decrease in deferred tax assets of $1.6 million, accretion and amortization of loan fees expense of $569,000, and a $298,000 loss on disposal of property and equipment. Partially offsetting these charges was a credit for the change in fair value of contingent purchase price consideration of $3.5 million. The cash used in operating assets and liabilities included a decrease in accounts payable and accrued liabilities of $5.0 million, an increase in inventory of $1.8 million and an increase in accounts receivable of $988,000 million, partially offset by an increase in other liabilities of $3.7 million. The decrease in accounts payable and accrued liabilities reflects the timing of certain payments. Inventory increased due to timing. The increase in accounts receivable reflects growing sales. The increase in other liabilities is mainly due to the long-term portion of the settlement with SSI.

Net cash used in operating activities from continuing operations was $27.3 million during the year ended December 31, 2016, which included a net loss of $21.6 million and cash used for changes in operating assets less liabilities of $12.1 million, partially offset by net non-cash items of $6.4 million. The cash used for changes in operating assets and liabilities included a decrease in accounts payable and accrued liabilities of $4.3 million, an increase in prepaid expenses and other assets of $3.1 million, an increase in accounts receivable, net of $1.6 million, a decrease in deferred income of $1.6 million, and an increase in inventory, net of $1.5 million. The decrease in accounts payable and accrued liabilities was largely due to the timing of payments. The increase in prepaid expenses and other assets largely reflects the timing of certain payments. The increase in accounts receivable, net reflects growing revenue during the year ended December 31, 2016 due to higher sales volumes, as well as the Imugen and Immunetics acquisitions. The decrease in deferred income primarily related to a change in the process used to determine pricing for certain sales to customers in Japan that has resulted in those sales being recorded upon shipment. The increase in inventory, net was largely due to timing. The non-cash items consisted of share-based compensation expense of $5.0 million, an intangible assets impairment charge of $1.8 million mainly related to IPR&D acquired from Boulder, depreciation and amortization expense of $932,000, and a $1.2 million credit from the change in fair value of contingent purchase price consideration.

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Investing activities from continuing operations

Net cash used in investing activities from continuing operations was $1.3 million and $28.4 million for the years ended December 31, 2017 and 2016, respectively. The cash used in 2017 consisted of purchases of property and equipment. The cash used in 2016 consisted of a net $27.5 million used to finance the acquisitions of Imugen and Immunetics and $856,000 used for purchases of property and equipment.

Financing activities from continuing operations

Net cash provided by financing activities from continuing operations was $39.4 million during the year ended December 31, 2017, which mainly reflected an offering that closed on August 18, 2017 and which resulted in approximately $39.3 million of net proceeds to us after deducting underwriting discounts and offering expenses. The offering closed on August 18, 2017.

Net cash provided by financing activities from continuing operations was $29.1 million during the year ended December 31, 2016, which mainly reflected a $30 million MidCap borrowing, net of related discount and debt issuance costs.

Discontinued operations

Net cash provided by discontinued operations for 2017 was $5.8 million, compared to $3.9 million for 2016.

Operating and capital expenditure requirements

We have not achieved operating profitability on a quarterly or annual basis since our inception and we expect to incur net losses in the future. We expect that our operating expenses will increase as we continue to invest to grow our customer base, expand our marketing and distribution channels, hire additional employees and increase product development expenditures. Additionally, as a public company, we incur significant audit, legal and other expenses. We believe that our existing capital resources will be sufficient to fund our operations for the next few years.

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

- our ability to continue to penetrate our existing markets and new markets in the United States;
- the costs and timing of further expansion of our sales and marketing efforts;
- our ability to penetrate existing markets outside the United States and enter and develop new geographies;
- the progress that we make in developing new products based on our technology platform;
- the percentage of sales that are reimbursed by payors and our ability to collect our accounts receivable;
- our ability to generate cash from operations; and
- the acquisition of businesses or technologies that we may undertake.

Contractual obligations

We have contractual obligations for non-cancelable facilities leases, equipment leases, license commitments and purchase commitments. Purchase commitments include future minimum royalty, license, and exclusivity payments to be paid under our license agreements with third parties for access to certain technologies. The following table reflects a summary of our contractual obligations as of December 31, 2018.

	Payments due by period				
(in thousands)	**Total**	**Less than 1 year**	**1-3 Years**	**3-5 Years**	**More than 5 years**
Operating lease obligations	$14,112	$2,024	$2,820	$1,710	$7,558
License commitments	1,268	262	193	118	695
Purchase commitments	8,723	8,723	—	—	—
Total	$24,103	$11,009	$3,013	$1,828	$8,253

Our U.K. corporate headquarters and manufacturing facility are located in Abingdon, England. We presently lease 8,600 square feet of manufacturing, storage and mixed use space pursuant to a lease that extends through December 31, 2020, or possibly sooner. Our rent for this space is currently $24,500 per month. We also rent separate warehouse/storage space in Abingdon, England near our corporate headquarters. The lease on the warehouse/storage space expires in 2025, and our current rent is $67,000 annually, which is subject to change.

In June 2018, the Company entered into a lease for a new space in Abingdon, England, which extends through June 30, 2033, or the 143 Park Lease. The 143 Park Lease covers 27,000 square feet of laboratory, office, storage and other mixed use space and will allow us to combine our current manufacturing, laboratory, storage and office operations into a single facility. Initial rent under the 143 Park Lease is approximately $39,000 per month. When the leases on the Company’s existing facilities have expired and it fully occupies the space subject to the 143 Park Lease, rent will increase to $79,000 per month. Rent will be reviewed for possible increases on June 1, 2021 and every third

anniversary after that date.

Our U.S. corporate headquarters is located in Marlborough, Massachusetts. In August 2015, we entered into a lease amendment on this location to extend the term of the lease by two years through October 31, 2020. In addition, beginning in March 2016, the lease amendment expanded our office space at this location by 7,600 square feet to a new total of 22,100 square feet. The base rent for the combined space over the lease term will range from an initial low of $36,000 per month, which includes $12,000 per month for the expansion space commencing in early 2016, to a high of $39,000 per month. We will have an option to extend the lease for one additional term of five years. We also currently sublease approximately 9,000 square feet of warehousing and office space from Quest in Norwood, Massachusetts. The base rent for this space is approximately $17,000 per month. The sublease expires in November 2020.

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In connection with the sale of the U.S. Laboratory Services Business to Quest Diagnostics Incorporated on November 6, 2018, approximately $32.3 million of the gross proceeds received pursuant to the Transaction, was paid directly to MidCap to repay the outstanding indebtedness under the MidCap agreement, which included prepayment and exit fees of approximately $2.3 million. In connection with the Company's repayment of the outstanding indebtedness under the MidCap Agreements, the Term Loan and the Revolving Loan, and all related agreements thereunder, were terminated and all borrowings outstanding thereunder were repaid in full.

Critical accounting policies and significant judgments and estimates

We have prepared our consolidated financial statements in accordance with U.S. GAAP. Our preparation of these consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, expenses and related disclosures at the date of the consolidated financial statements, as well as revenue and expenses during the reporting periods. We evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results could therefore differ materially from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 1. *Description of business and significant accounting policies*, to our consolidated financial statements included in this Annual Report on Form 10-K, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our financial statements.

Revenue recognition and accounts receivable

The Company's revenues include product and service revenues. Product revenue from diagnostic test kit sales and related accessories is recognized at a point in time based upon contractual rates. Service revenue from tests performed on samples sent by direct billing customers is recorded based upon contractually established billing rates and recognized upon delivery of test results to the customer. Revenue from tests paid by third-party payors in the U.S. includes variable consideration, which is estimated using the expected value method based on the Company's historical collection experience.

As of December 31, 2018, accounts receivables related to products and services were $9.2 million. For the year ended December 31, 2018, the Company had no material bad-debt expense and there were no material contract assets, contract liabilities or deferred contract costs recorded on the Consolidated Balance Sheet as of December 31, 2018. The Company generally expenses sales commissions when incurred because the amortization period would be less

than one year.

Revenue expected to be recognized in any future year related to remaining performance obligations is not material.

Income taxes

We account for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax basis of our assets and liabilities and their financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses, or NOLs, and research and development credit carryforwards. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

We follow the accounting guidance for uncertainties in income taxes, which prescribes a recognition threshold and measurement process for recording uncertain tax positions taken, or expected to be taken, in tax returns. Additionally, the guidance also prescribes the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. We accrue for the estimated amount of taxes for uncertain tax positions if it is more likely than not that we would be required to pay such additional taxes. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. We did not have any accrued interest or penalties associated with any unrecognized tax positions, and there were no such interest or penalties recognized during the years ended December 31, 2018, 2017 or 2016.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the TCJA, was enacted. This tax reform legislation made significant changes in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the current rate of 34% to 21% effective on January 1, 2018. As a result of the enacted law, the Company was required to revalue deferred tax assets and liabilities at the 21% rate. This resulted in a decrease in the company’s net deferred tax asset and corresponding valuation allowance of $19.8 million. As the Company maintains a full valuation allowance against its net deferred tax asset position in the United States, this revaluation did not result in an income tax expense or benefit in 2017. The other provisions of the TCJA did not have a material impact on the Company’s consolidated financial statements.

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Share-based compensation

Share-based compensation relates to grants of options to purchase ordinary shares, restricted shares and restricted share units. Currently, we maintain two equity compensation plans, the Amended and Restated 2008 Stock Incentive Plan and the 2013 Share Incentive Plan. With the adoption of the 2013 Share Incentive Plan, we are no longer authorized to grant awards under the Amended and Restated 2008 Stock Incentive Plan.

We measure the cost of equity-settled transactions with employees by reference to the fair value of the equity instruments at the date on which they are granted. Estimating fair value for options requires determining the most appropriate valuation model, which is dependent on the terms and conditions of the grant. This estimate also requires determining the most appropriate inputs to the valuation model, including the expected life of the award, volatility and dividend yield, and making certain assumptions about the award. Share-based compensation expense for restricted shares is calculated based on the grant date market price of the shares and is recognized over the vesting period.

We use the Black-Scholes option pricing model to value the share option awards. The Black-Scholes option pricing model requires the input of subjective assumptions, including assumptions about the expected life of share-based payment awards and share price volatility. In addition, when we were a private company, one of the most subjective inputs into the Black-Scholes option pricing model was the estimated fair value of our ordinary shares. Due to the lack of an adequate history of a public market for the trading of our ordinary shares and a lack of adequate company specific historical and implied volatility data, we have based our estimate of expected volatility in part on our volatility, as well as on the historical volatility of a group of similar companies that are publicly traded. For these analyses, we have selected companies with comparable characteristics to ours including enterprise value, risk profiles, position within the industry, and with historical share price information sufficient to meet the expected life of the share-based awards. We compute the historical volatility data using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of our share-based awards. We will continue to apply this process until a sufficient amount of historical information regarding the volatility of our own share price becomes available.

We determine the expected term for share option grants to employees based on the “simplified” method prescribed under Staff Accounting Bulletin Topic 14: Share-based Payments. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option. The risk-free interest rate is a weighted-average assumption equivalent to the expected term based on the United States Treasury yield curve in effect as of the date of grant. The assumptions used in calculating the fair value of the share-based payment awards represent our best estimate and involve inherent uncertainties and the application of our judgment. As a result, if factors change and we use different assumptions, share-based compensation expense could be materially different in the future.

In accordance with Financial Accounting Standards Board, Accounting Standards Codification 718, *Compensation—Stock Compensation*, we recognize expense based on the share option grant's pre-defined vesting schedule over the requisite service period using the straight-line method for all employee share options. In addition to the assumptions used to calculate the fair value of the share options, we elected to estimate the expected forfeiture rate of all share-based awards and only recognize expense for those awards expected to vest. The estimation of the number of share awards that will ultimately vest requires judgment, and to the extent actual results or updated estimates differ from our current estimates, such amounts will be recorded as a cumulative adjustment in the period in which estimates are revised. We consider multiple factors when estimating expected forfeitures, including employee position and historical employee turnover data. During the period in which the share options vest, we will record additional expense if the actual forfeiture rate is lower than the estimated forfeiture rate and a recovery of expense if the actual forfeiture rate is higher than estimated.

Business combinations

For acquisitions meeting the definition of a business combination, we allocate the purchase price, including any contingent consideration, to the assets acquired and the liabilities assumed at their estimated fair values as of the date of the acquisition with any excess of the purchase price paid over the estimated fair value of net assets acquired recorded as goodwill. The fair value of the assets acquired and liabilities assumed is typically determined by using either estimates of replacement costs or discounted cash flow valuation methods.

When determining the fair value of tangible assets acquired, we estimate the cost using the most appropriate valuation method with assistance from independent third-party specialists. When determining the fair value of intangible assets acquired, we use judgment to estimate the applicable discount rate, growth rates and the timing and amount of future cash flows. The fair value of assets acquired and liabilities assumed is typically determined by management using the assistance of independent third-party specialists. The assumptions used in calculating the fair value of tangible and intangible assets represent our best estimates. If factors change and we were to use different assumptions, valuations of tangible and intangible assets and the resulting goodwill balance related to the business combination could be materially different.

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Goodwill

Goodwill is not amortized but is reviewed for impairment at least annually in the fourth quarter of the year, or when events or changes in the business environment indicate that all, or a portion, of the carrying value of the reporting unit may no longer be recoverable, using the two-step impairment review. Under this method, we compare the fair value of the goodwill to its carrying value. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine if goodwill is impaired. An impairment loss, if any, is measured as the excess of the carrying value of goodwill over the fair value of goodwill. We also have the option to first assess qualitative factors to determine whether the existence of events or circumstances leads us to determine that it is more likely than not (that is, a likelihood of more than 50%) that goodwill is impaired. If we choose to first assess qualitative factors and it is determined that it is not more likely than not goodwill is impaired, we are not required to take further action to test for impairment. We also have the option to bypass the qualitative assessment and perform only the quantitative impairment test, which we may choose to do in some periods but not in others.

Off-balance sheet arrangements

We do not have any relationships with unconsolidated entities or financial partnerships, such as entities often referred to as structured finance or special purpose entities, which would have been established for the purpose of facilitating off-balance sheet arrangements or for any other contractually narrow or limited purpose.

Recent accounting pronouncements

See Note 1. *Description of business and significant accounting policies*, to our consolidated financial statements included in this Annual Report on Form 10-K for a discussion of the impact of recent accounting pronouncements on our consolidated financial statements.

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Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2018, we had cash and cash equivalents of $192.8 million.

We are exposed to market risks in the ordinary course of our business. These market risks are principally limited to interest rate fluctuations, capital market fluctuations and foreign currency exchange rate fluctuations, as discussed below.

Interest rate fluctuations

Changes in the general level of U.S. and European interest rates expose us to interest rate risk. These changes could affect our interest income. Based on our cash and cash equivalents at December 31, 2018, if interest rates went either up or down one percentage point, this could change our interest income by approximately $1.8 million per annum.

Capital market fluctuations

Our cash and cash equivalents are invested in interest-bearing savings and money market accounts. We do not enter into investments for trading or speculative purposes. We do not believe capital market fluctuations would have a material effect on the fair market value of our portfolio.

Foreign currency exchange rate fluctuations

We are exposed to foreign exchange rate risk because we currently operate in three major regions of the world: the United States, Europe and ROW and Asia, and our revenue is denominated in multiple currencies. Approximately 28% of our sales during the year ended December 31, 2018 were in the United States, which are denominated in U.S. Dollars. Sales in China and South Korea are also denominated in U.S. Dollars but these sales are made by our United Kingdom-based subsidiary where the Pound Sterling is the functional currency. As a result, these sales are subject to remeasurement into Pounds Sterling and then translation into U.S. Dollars when we consolidate our financial statements. Sales in Europe are denominated primarily in the Pound Sterling and Euro. As we grow Europe and ROW sales outside the United Kingdom and the Euro Zone, we may be subject to risk from additional currencies. Sales in Japan are denominated in Yen.

Our expenses are generally denominated in the currencies in which our operations are located, which are primarily in the United States, the United Kingdom, Japan, Europe, China and South Korea.

As we continue to grow our business outside the United States, our results of operations and cash flows will be subject to fluctuations due to changes in foreign currency exchange rates, which could harm our business in the future. To date, we have not entered into any foreign currency hedging contracts, although we may do so in the future.

Item 8. Financial Statements and Supplementary Data

The information required by this item may be found beginning on page F-1 of this Annual Report on Form 10-K with the exception of the unaudited consolidated quarterly operations data, which is presented below. Net income (loss) per ordinary share amounts are calculated independently for each of the periods presented. Therefore, the sum of the quarterly net income (loss) per ordinary share amounts will not necessarily equal the total for the full fiscal year.

We have prepared the consolidated quarterly operations data on a consistent basis with the audited consolidated financial statements included elsewhere in this Annual Report on Form 10-K. In the opinion of management, the quarterly consolidated operations data reflects all necessary adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of these data. Historical results are not necessarily indicative of the results to be expected in future periods, and the results for a quarterly period are not necessarily indicative of the operating results for a full year. This information should be read in conjunction with the consolidated financial statements included elsewhere in this Annual Report Form 10-K.

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On November 6, 2018, Quest Diagnostics Incorporated completed its acquisition of the Company's U.S. Laboratory Services Business. This agreement represents a strategic business shift having a major effect on the Company's operations and financial results. Accordingly, the operations of this business have been reported in discontinued operations in the consolidated financial statements for all periods presented. Therefore, results of discontinued operations have been broken-out in the quarterly data presented below.

	Three months ended			
(in thousands, except share and per share data) (unaudited)	**March 31, 2018**	**June 30, 2018**	**September 30, 2018**	**December 31, 2018**
Revenue:				
Product	$10,129	$15,012	$ 15,095	$ 14,451
Service	1,550	1,645	955	916
Total revenue	$11,679	$16,657	$ 16,050	$ 15,367
Gross profit	$7,920	$12,119	$ 11,477	$ 11,411
(Loss) income from continuing operations	$(8,186)	$(5,733)	$ (6,258)	$ 32,682
(Loss) income from discontinued operations	(2,140)	(738)	2,774	108,378
Net (loss) income [1]	$(10,326)	$(6,471)	$ (3,484)	$ 141,060
Net (loss) income per ordinary share—basic:				
(Loss) income from continuing operations	$(0.32)	$(0.22)	$ (0.24)	$ 1.24
(Loss) income from discontinued operations	$(0.08)	$(0.03)	$ 0.11	$ 4.12
Net (loss) income	$(0.40)	$(0.25)	$ (0.13)	$ 5.36
Net (loss) income per ordinary share—diluted:				
(Loss) income from continuing operations	$(0.32)	$(0.22)	$ (0.24)	$ 1.22
(Loss) income from discontinued operations	$(0.08)	$(0.03)	$ 0.11	$ 4.06
Net (loss) income	$(0.40)	$(0.25)	$ (0.13)	$ 5.28
Weighted-average shares used to compute net (loss) income per ordinary share—basic	25,718,910	25,845,124	26,033,550	26,326,419
Weighted-average shares used to compute net (loss) income per ordinary share—diluted	25,718,910	25,845,124	26,033,550	26,697,589

	Three months ended			
(in thousands, except share and per share data) (unaudited)	**March 31, 2017**	**June 30, 2017**	**September 30, 2017**	**December 31, 2017**
Revenue:				
Product	$10,770	$13,523	$13,419	$11,187
Service	1,395	1,434	1,592	1,413
Total revenue	$12,165	$14,957	$15,011	$12,600
Gross profit	$7,840	$9,687	$9,764	$8,972
(Loss) income from continuing operations	$(6,525)	$(15,590)	$(19,497)	$8,386
(Loss) income from discontinued operations	(1,547)	(1,176)	2,650	414
Net (loss) income [2]	$(8,072)	$(16,766)	$(16,847)	$8,800
Net (loss) income per ordinary share—basic:				
(Loss) income from continuing operations	$(0.29)	$(0.68)	$(0.81)	$0.33
(Loss) income from discontinued operations	$(0.07)	$(0.05)	$0.11	$0.02

Net (loss) income [3]	$(0.36)	$(0.74)	$(0.70)	$0.34
Net (loss) income per ordinary share—diluted:				
(Loss) income from continuing operations	$(0.29)	$(0.68)	$(0.81)	$0.31
(Loss) income from discontinued operations	$(0.07)	$(0.05)	$0.11	$0.02
Net (loss) income [3]	$(0.36)	$(0.74)	$(0.70)	$0.33
Weighted-average shares used to compute net (loss) income per ordinary share:				
Basic	22,533,531	22,805,379	24,123,574	25,532,152
Diluted	22,533,531	22,805,379	24,123,574	26,828,912

(1) The three months ended December 31, 2018 included a $146.0 million gain on the sale of our U.S. Laboratory Services Business to Quest pursuant to a Limited Liability Company Interest Purchase Agreement from which we received approximately $130.2 million in cash proceeds. Upon closing of the Transaction, approximately $32.3 million was paid directly to MidCap in settlement of all amounts due, which included prepayment and exit fees of approximately $2.3 million.

(2) The three months ended June 30, 2017 included a $9.6 million Release and Settlement Agreement, or the Settlement Agreement, with Statens Serum Institut, or SSI, to resolve outstanding disputes arising from our previous license agreement. The terms of the Settlement Agreement are confidential. Based on the Settlement Agreement, we no longer expect to pay royalties to SSI, which will improve future margins. The three months ended September 30, 2017 included an impairment charge of $11.1 million to write-off certain intangibles acquired in conjunction with the 2016 acquisition of Imugen, including $9.2 million related to IPR&D, $1.1 million related to customer relationships and $701,000 related to the Imugen trade name. The three months ended December 31, 2017 included a $27.5 million one-time, lump-sum payment for the settlement of a lawsuit. See Part I, Item 3. Legal Proceedings for further information. Additionally, the three months ended December 31, 2017 included an impairment charge of $7.2 million to write-off certain intangibles acquired in conjunction with the 2016 acquisition of Immunetics.

(3) Net (loss) income per ordinary share amounts may not equal the sums of the respective columns due to rounding.

Our revenue fluctuates from quarter-to-quarter as a result of a number of factors, many of which are outside our control. Additionally, we see fluctuation in our product revenue from quarter to quarter, due to ordering patterns, particularly relating to our large distributor customers. As a result of such factors, we expect to continue to see quarter-to-quarter variations in our revenue.

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Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure

There have been no changes in or disagreements with accountants on accounting and financial disclosure matters in the last fiscal year.

Item 9A. Controls and procedures

(a) Evaluation of disclosure controls and procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) as of the end of the period covered by this Form 10-K. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were not effective due to a material weakness in our internal controls relating to income tax accounting that existed as of December 31, 2018, as discussed below.

(b) Management's report on internal control over financial reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Securities Exchange Act Rule 13a-15(f). Management, including our Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2018. In making this assessment, management used the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on this assessment, management has concluded that we did not maintain effective internal control over financial reporting as of December 31, 2018 because of the material weakness identified below. A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the Company's annual or interim financial statements will not be prevented or detected on a timely basis.

We did not design and maintain effective internal control over the accounting for income taxes, including the income tax provision, deferred tax assets and liabilities and related disclosures. Specifically, we did not have sufficient technical expertise in the income tax function to review with a level of precision that would have identified a material misstatement in the income tax provision, including the allocation of tax between continuing and discontinued operations as well as the calculation of deferred tax assets and liabilities and related disclosures. Management and the

Audit Committee believe that the complexity introduced to the Company's financial statements as a result of the sale of the Company's U.S. laboratory service business to Quest, or the Transaction, was a contributing factor to the identified deficiencies.

Oxford Immunotec Global PLC's independent registered public accounting firm, Ernst & Young LLP, has audited the Company's internal control over financial reporting as of December 31, 2018, as stated in their report, which appears herein.

(c) Remediation of Material Weakness

Under the oversight of our Audit Committee, we are committed to improving our internal controls processes and resolving the material weakness we have presented above. As we continue to evaluate and work to improve our internal control over financial reporting, we may implement additional measures or modify the remedial actions described below, as considered appropriate, to remediate our material weakness.

Management's preliminary assessment of a remediation plan to address the control deficiencies that led to the material weakness includes the following:

i. enhancing corporate tax accounting resources to strengthen tax accounting review procedures;
ii. reassessing the design of our tax review controls to identify areas where enhanced precision will help detect and prevent material misstatements; and
iii. assessing the involvement of a third party provider.

Management will report regularly to the Audit Committee regarding the status of the implementation of the remediation activities. Our goal is to remediate this material weakness by the end of 2019, subject to there being sufficient opportunities to conclude, through testing, that the enhanced controls are operating effectively.

(d) Changes in internal control over financial reporting

On November 6, 2018, we completed the sale of our U.S. Laboratory Services Business to Quest. As a result of the Transaction, certain U.S. service business controls were eliminated in the fourth quarter of 2018. The Company also added new controls relating to the divestiture process. In conjunction with the Transaction, a newly formed wholly owned subsidiary of Oxford Immunotec Limited, Oxford Immunotec USA, Inc., was incorporated into our existing internal control processes.

Other than with respect to our sale of the U.S. Laboratory Services Business to Quest as described above and the material weakness discussed herein, there have been no changes to our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the fourth quarter of 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other information

None.

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PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2018.

Item 11. Executive Compensation

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2018.

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

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2018.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2018.

Item 14. Principal Accounting Fees and Services

The information required under this item is incorporated herein by reference to our definitive proxy statement pursuant to Regulation 14A, to be filed with the Commission not later than 120 days after the close of our fiscal year ended December 31, 2018.

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PART IV

Item 15. Exhibits, Financial Statement Schedules

(a)1. Financial Statements

As part of this Annual Report on Form 10-K, the consolidated financial statements are listed in the accompanying index to financial statements on page F-1.

2. Financial Statement Schedules

All schedules have been omitted because they are not required, not applicable, not present in amounts sufficient to require submission of the schedule, or the required information is otherwise included.

3. Exhibit Index

The following is a list of exhibits filed as part of this Annual Report on Form 10-K:

Exhibit number	Description of exhibit
2.1*+	Purchase Agreement, dated June 23, 2016, between Oxford Immunotec, Inc. and Imugen, Inc. (Filed as Exhibit 2.1 to our Current Report on Form 8-K on July 6, 2016, and incorporated herein by reference.)
2.2+†	Limited Liability Company Interest Purchase Agreement by and among Quest Diagnostics Incorporated, Oxford Immunotec Limited, Oxford Immunotec, Inc. and solely for the purposes of Section 5.4, Section 5.6, Section 5.12, Section 5.16, Article VII and Article IX, Oxford Immunotec Global PLC (Filed as Exhibit 2.1 of our Form 8-K on September 25, 2018 and incorporated herein by reference)
3.1	Articles of Association of the Registrant (Filed as Exhibit 3.1 of our Form 8-K on June 18, 2014 and incorporated herein by reference.)
4.1	Form of Ordinary Shares Certificate (Filed as Exhibit 4.1 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)

10.1+	Supply Agreement dated December 17, 2010 between MicroCoat Biotechnologie GmbH and Oxford Immunotec Limited (Filed as Exhibit 10.11 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.2	Amendment to Supply Agreement dated April 5, 2016 between MicroCoat Biotechnologie GmbH and Oxford Immunotec Limited (Filed as Exhibit 10.2 to our Quarterly Report on Form 10-K on May 4, 2016, and incorporated herein by reference.)
10.3+	Purchase Agreement dated February 6, 2010 between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.12 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.4+	Amendment to Purchase Agreement dated September 10, 2013 between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.13 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.5+	Second Amendment to Purchase Agreement between Mabtech AB and Oxford Immunotec Limited dated November 17, 2017 (Filed as Exhibit 10.5 of our Annual Report on Form 10-K on February 27, 2018 and incorporated herein by reference.)
10.6+	Manufacturing Agreement dated August 26, 2003 between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.14 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.7	First Amendment dated January 1, 2010 to Manufacturing Agreement between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.15 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.8	Second Amendment dated May 24, 2011 to Manufacturing Agreement between Mabtech AB and Oxford Immunotec Limited (Filed as Exhibit 10.16 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.9+	Supply Agreement dated January 31, 2008 between StemCell Technologies, Inc. and Oxford Immunotec Limited (Filed as Exhibit 10.19 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)

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Exhibit number	Description of exhibit
10.10+	Amendment dated October 26, 2011 to Supply Agreement between StemCell Technologies, Inc. and Oxford Immunotec Limited (Filed as Exhibit 10.20 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.11+	Second Amendment to Supply Agreement dated September 1, 2017 between StemCell Technologies Canada Inc. f/k/a StemCell Technologies, Inc. and Oxford Immunotec Limited (Filed as Exhibit 10.1 of our Form 10-Q on October 31, 2017 and incorporated herein by reference.)
10.12+	Supplier Agreement dated January 7, 2019 between Millipore (UK) Ltd. and Oxford Immunotec Limited.
10.13+	Amended and Restated Supply and Reseller Agreement dated January 9, 2019 between Life Technologies Corporation and Oxford Immunotec Limited
10.14+	Distributorship Agreement dated October 8, 2013 among Shanghai Fosun Long March Medical Science Co. Ltd., Shanghai Xin Chang Medical Device Co. Ltd. and Oxford Immunotec Limited (Filed as Exhibit 10.24 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.15+	First Amendment to Distributorship Agreement between Oxford Immunotec, Ltd., Fosun Long March Medical Science Co. Ltd. and Shanghai Xin Chang Medical Device Co. Ltd. dated April 22, 2015 (Filed as Exhibit 10.1 of our Quarterly Report on Form 10-Q on August 4, 2015 and incorporated herein by reference.)
10.16+	Second Amendment to Distributorship Agreement between Oxford Immunotec, Ltd., Fosun Long March Medical Science Co. Ltd. and Shanghai Xin Chang Medical Device Co. Ltd. dated November 3, 2016. (Filed as Exhibit 10.20 of our Annual Report on Form 10-K on March 1, 2017 and incorporated herein by reference.)
10.17+	Third Amendment to Distributorship Agreement between Oxford Immunotec, Ltd., Fosun Long March Medical Science Co. Ltd. and Shanghai Xin Chang Medical Device Co. Ltd. entered into on December 20, 2017(Filed as Exhibit 10.21 of our Annual Report on Form 10-K on February 27, 2018 and incorporated herein by reference.)
10.18+	Fourth Amendment to Distributorship Agreement between Oxford Immunotec, Ltd., Fosun Long March Medical Science Co. Ltd. and Shanghai Xin Chang Medical Device Co. Ltd. dated June 5, 2018 (Filed as Exhibit 10.1 of our Quarterly Report on Form 10-Q on July 31, 2018 and incorporated herein by reference.)
10.19+	Fifth Amendment to Distributorship Agreement between Oxford Immunotec, Ltd., Fosun Long March Medical Science Co. Ltd. and Shanghai Xin Chang Medical Device Co. Ltd. dated September 17, 2018 (Filed as Exhibit 10.1 of our Quarterly Report on Form 10-Q on November 9, 2018 and incorporated herein by reference.)
10.20+	Marketing Authorization Holder Agreement dated July 29, 2011 between Riken Genesis Co., Ltd. and Oxford Immunotec Limited (Filed as Exhibit 10.25 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)

10.21+	Amendment to Marketing Authorization Holder Agreement dated September 1, 2013 between Riken Genesis Co., Ltd. and Oxford Immunotec Limited (Filed as Exhibit 10.26 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.22	Amendment to Marketing Authorization Holder Agreement dated April 1, 2016 between Riken Genesis Co., Ltd. and Oxford Immunotec Limited (Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q on May 4, 2016, and incorporated herein by reference.)
10.23	Amendment to Marketing Authorization Holder Agreement dated July 7, 2017 between Riken Genesis Co., Ltd. and Oxford Immunotec Limited (Filed as Exhibit 10.1 of our Form 8-K on July 28, 2017 and incorporated herein by reference.)
10.24	Amended and Restated 2008 Stock Incentive Plan (Filed as Exhibit 10.35 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.25	Oxford Immunotec Global PLC 2013 Share Incentive Plan (Filed as Exhibit 10.39 of Amendment No. 6 of our Registration Statement on Form S-1 (File No. 333-191737) on November 14, 2013 and incorporated herein by reference.)
10.26	Oxford Immunotec Global PLC 2013 Amended Share Incentive Plan (Filed as Exhibit 10.33 of our Annual Report on Form 10-K on February 27, 2018 and incorporated herein by reference.)
10.27	Form of Director Stock Option Award under Oxford Immunotec Global PLC 2013 Share Incentive Plan (Filed as Exhibit 10.48 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)

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Exhibit number	Description of exhibit
10.28	Form of Restricted Share Award Certificate under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United States (Filed as Exhibit 10.2 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.29	Form of Restricted Share Award Certificate under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.1 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.30	Form of First Amendment to Officer Restricted Share Award (Double Trigger) under Appendix C of the 2013 Share Incentive Plan (Filed as Exhibit 10.1 of our Form 8-K on January 2, 2015 and incorporated herein by reference.)
10.31	Form of First Amendment to Officer Stock Option Award under Appendix D of the 2013 Share Incentive Plan (Filed as Exhibit 10.2 of our Form 8-K on January 2, 2015 and incorporated herein by reference.)
10.32	Form of CSOP Option Certificate (Annual Vesting) under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.39 of our Annual Report on Form 10-K on March 1, 2016 and incorporated herein by reference).
10.33	Form of Unapproved Stock Option Award (Annual Vesting) under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.41 of our Form 10-K on March 1, 2016 and incorporated herein by reference).
10.34	Form of Stock Option Agreement (Annual Vesting) under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United States (Filed as Exhibit 10.43 of our Annual Report on Form 10-K on March 1, 2016 and incorporated herein by reference).
10.35	Form of Unapproved Stock Option Award (Double Trigger) under the Oxford Immunotec Global PLC 2013 Share Incentive Plan (Filed as Exhibit 10.44 of our Annual Report on Form 10-K on February 27, 2018 and incorporated herein by reference.)
10.36	Form of Restricted Share Unit Award under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers (Filed as Exhibit 10.44 of our Annual Report on Form 10-K on March 1, 2016 and incorporated herein by reference).
10.37	Service Agreement dated October 21, 2002 between Oxford Immunotec Limited and Peter Wrighton-Smith, as amended through 2013 (Filed as Exhibit 10.45 of our Annual Report on Form 10-K on March 27, 2014 and incorporated herein by reference.)
10.38	Deed of Novation of Agreement for Services dated November 8, 2013 by and among Oxford Immunotec Limited, Oxford Immunotec Global PLC and Peter Wrighton-Smith (Filed as Exhibit 10.49 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)
10.39	Amended and Restated Employment Agreement dated October 1, 2013 between Oxford Immunotec, Inc. and Richard M. Altieri (Filed as Exhibit 10.43 of our Registration Statement on Form S-1 (File No. 333-191737)

	on October 15, 2013 and incorporated herein by reference.)
10.40	Form of Employment Agreement for Senior Executives (Filed as Exhibit 10.50 of our Annual Report on Form 10-K on February 27, 2018 and incorporated herein by reference.)
10.41	Form of Deed of Indemnity for Directors (Filed as Exhibit 10.44 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)
10.42	Form of Deed of Indemnity for Officers (Filed as Exhibit 10.45 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-191737) on November 8, 2013 and incorporated herein by reference.)
10.43	Form of Non-Executive Director Appointment Letter (Filed as Exhibit 10.46 of Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-191737) on November 4, 2013 and incorporated herein by reference.)
10.44	Agreement to Purchase Test Kits and Accessories dated November 6, 2018 between Quest Diagnostics Incorporated and Oxford Immunotec USA, Inc. (Filed as Exhibit B to the IPA filed as Exhibit 2.1 of our Form 8-K on September 25, 2018 and incorporated herein by reference)
10.45	Form of Bonus Agreement (Filed as Exhibit 10.2 of our Quarterly Report on Form 10-Q on November 9, 2018 and incorporated herein by reference)
10.46	Form of Bonus Agreement (Filed as Exhibit 10.3 of our Quarterly Report on Form 10-Q on November 9, 2018 and incorporated herein by reference)
10.47	Separation Agreement dated March 8, 2019 between Richard A. Wenstrup and Oxford Immunotec USA, Inc.

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Exhibit number	Description of exhibit
21.1	List of Subsidiaries
23.1	Consent of Ernst & Young LLP (US)
23.2	Consent of Ernst & Young LLP (UK)
24.1	Power of Attorney executed by Directors and Officers (included on signature page)
31.1	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated balance sheets as of December 31, 2018 and 2017; (ii) Consolidated statements of operations for the years ended December 31, 2018, 2017 and 2016; (iii) Consolidated statements of other comprehensive income (loss) for the years ended December 31, 2018, 2017 and 2016; (iv) Consolidated statements of shareholders' equity for the years ended December 31, 2018, 2017 and 2016; (v) Consolidated statements of cash flows for the years ended December 31, 2018, 2017 and 2016; and (vi) Notes to consolidated financial statements.

* All schedules (and similar attachments) to the Purchase Agreement were omitted pursuant to Section 601(b)(2) of Regulation S-K. The Registrant hereby agrees to furnish supplementally a copy of any omitted schedule (or other attachment) to the SEC.

+ Confidential treatment has been granted or requested with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the SEC.

† Certain exhibits and schedules to the Purchase Agreement have been omitted pursuant to Item 601(b)(2) of Regulation S-K. A copy of any omitted schedule and exhibit will be furnished supplementally to the Securities and Exchange Commission upon request.

Item 16. Form 10-K Summary

None.

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Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Abingdon, England, on March 27, 2019.

OXFORD IMMUNOTEC GLOBAL PLC

By: /s/ Peter Wrighton-Smith, Ph.D.
Peter Wrighton-Smith, Ph.D.

Chief Executive Officer and Director

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Peter Wrighton-Smith, Ph.D., Richard M. Altieri, and Elizabeth M. Keiley, and each of them, as his or her true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this Annual Report on Form 10-K, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he or she might or could do in person, hereby ratifying and confirming that all said attorneys-in-fact and agents, or any of them or their or his or her substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant on March 27, 2019 in the capacities indicated below.

Signature	Title	Date
/s/ Peter Wrighton-Smith, Ph.D. Peter Wrighton-Smith, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	March 27, 2019
/s/ Richard M. Altieri Richard M. Altieri	Chief Financial Officer (Principal Financial and Accounting Officer)	March 27, 2019

/s/ Richard A. Sandberg Richard A. Sandberg	Chairman of the Board of Directors	March 27, 2019
/s/ Ronald Andrews Jr. Ronald Andrews Jr.	Director	March 27, 2019
/s/ Patrick J. Balthrop, Sr. Patrick J. Balthrop, Sr.	Director	March 27, 2019
/s/ Mark Klausner Mark Klausner	Director	March 27, 2019
/s/ Patricia Randall Patricia Randall	Director	March 27, 2019
/s/ Herm Rosenman Herm Rosenman	Director	March 27, 2019
/s/ James R. Tobin James R. Tobin	Director	March 27, 2019
/s/ A. Scott Walton A. Scott Walton	Director	March 27, 2019
/s/ Richard M. Altieri Richard M. Altieri	Authorized Representative in the United States	March 27, 2019

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Oxford Immunotec Global PLC

Index to financial statements

Audited consolidated financial statements

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Oxford Immunotec Global Plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Oxford Immunotec Global Plc (the Company) as of December 31, 2018, the related consolidated statements of income, comprehensive income**,** shareholders' equity and cash flows for the year ended December 31, 2018, 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 December 31, 2018, and the results of its operations and its cash flows for the year ended December 31, 2018, in conformity with U.S. generally accepted accounting principles.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), and our report dated March 27, 2019 expressed an adverse opinion thereon.

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 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. 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 a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2018.

Boston, Massachusetts

March 27, 2019

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Oxford Immunotec Global Plc

Opinion on Internal Control over Financial Reporting

We have audited Oxford Immunotec Global Plc's internal control over financial reporting as of December 31, 2018, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 framework), (the COSO criteria). In our opinion, because of the effect of the material weakness described below on the achievement of the objectives of the control criteria, Oxford Immunotec Global Plc (the Company) has not maintained effective internal control over financial reporting as of December 31, 2018, based on the COSO criteria.

A material weakness is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company's annual or interim financial statements will not be prevented or detected on a timely basis. The following material weakness has been identified and included in management's assessment. Management has identified a deficiency in controls related to the accounting for income taxes, including the income tax provision and related tax assets and liabilities, and has concluded that such deficiency represented a material weakness as of December 31, 2018.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the accompanying consolidated balance sheets of the Company as of December 31, 2018, the related consolidated statements of income, comprehensive income**,** shareholders' equity and cash flows for the year ended December 31, 2018, and the related notes. This material weakness was considered in determining the nature, timing, and extent of audit tests applied in our audit of the 2018 consolidated financial statements, and this report does not affect our report dated March 27, 2019 which expressed an unqualified opinion thereon.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the 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 effective internal control over financial reporting was maintained in all material respects.

Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, testing and evaluating the design and operating effectiveness of internal control based on the assessed risk, and performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. 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.

/s/ Ernst & Young LLP

Boston, Massachusetts

March 27, 2019

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Report of Independent Registered Public Accounting Firm

To the Shareholders and the Board of Directors of Oxford Immunotec Global PLC

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheet of Oxford Immunotec Global PLC (the Company) as of December 31, 2017, the related consolidated statements of operations, other comprehensive loss, shareholders' equity and cash flows for each of the two years in the period ended December 31, 2017, 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 December 31, 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2017, 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 served as the Company's auditor from 2006 to 2018.

Reading, United Kingdom

February 27, 2018, except for the effects of discontinued operations described in Notes 1 and 19, as to which the date is March 27, 2019

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Oxford Immunotec Global PLC

Consolidated balance sheets

(in thousands, except share and per share data)

	December 31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$192,844	$90,332
Accounts receivable, net	9,158	6,021
Other receivable	4,500	—
Inventory, net	7,767	7,137
Prepaid expenses and other assets	2,511	2,711
Current assets of discontinued operations	—	14,281
Total current assets	216,780	120,482
Restricted cash, non-current	100	200
Other receivable	4,500	—
Property and equipment, net	7,144	2,764
Goodwill	2,483	2,483
Other intangible assets, net	61	1,036
Deferred tax asset	1,052	2,486
Noncurrent assets of discontinued operations	—	14,785
Total assets	$232,120	$144,236
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	$2,801	$5,552
Accrued liabilities	10,891	7,807
Settlement liability	4,106	4,342
Deferred income	125	36
Current portion of loans payable	85	78
Current liabilities of discontinued operations	—	4,630
Total current liabilities	18,008	22,445
Long-term portion of loans payable	106	29,856
Settlement liability	—	3,894
Other liabilities	—	364
Noncurrent liabilities of discontinued operations	—	48
Total liabilities	18,114	56,607
Commitments and contingencies (Notes 3, 9, and 16)		

Shareholders' equity:		
Ordinary shares, £0.006705 nominal value; 38,978,604 and 36,183,293 shares authorized at December 31, 2018 and 2017, respectively, 26,439,334 and 25,661,634 shares issued and outstanding at December 31, 2018 and 2017, respectively	276	269
Additional paid-in capital	303,015	294,613
Accumulated deficit	(80,762)	(201,541)
Accumulated other comprehensive loss	(8,523)	(5,712)
Total shareholders' equity	214,006	87,629
Total liabilities and shareholders' equity	$232,120	$144,236

See accompanying notes to these consolidated financial statements.

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Oxford Immunotec Global PLC

Consolidated statements of operations

(in thousands, except share and per share data)

	Year ended December 31,		
	2018	**2017**	**2016**
Revenue:			
Product	$54,687	$48,899	$43,070
Service	5,066	5,834	3,918
Total revenue	59,753	54,733	46,988
Cost of revenue:			
Product	13,668	13,864	13,807
Service	3,158	4,606	2,684
Total cost of revenue	16,826	18,470	16,491
Gross profit	42,927	36,263	30,497
Operating expenses:			
Research and development	8,122	10,835	9,370
Sales and marketing	26,500	29,053	26,858
General and administrative	25,952	25,450	18,918
Change in fair value of contingent purchase price consideration	—	(3,475)	(1,208)
Intangible assets impairment charge	879	18,300	1,765
Settlement expense	2,193	10,028	—
Total operating expenses	63,646	90,191	55,703
Operating loss from continuing operations	(20,719)	(53,928)	(25,206)
Other income (expense):			
Interest expense, net	(1,797)	(3,105)	(864)
Loss on extinguishment of debt	(2,105)	—	—
Foreign exchange gains (losses)	111	(1,850)	1,364
Other expense	(271)	(209)	(646)
Litigation settlement income	—	27,500	—
Loss from continuing operations before income taxes	(24,781)	(31,592)	(25,352)
Income tax benefit (expense) from continuing operations	37,286	(1,634)	3,774
Income (loss) from continuing operations	12,505	(33,226)	(21,578)
Discontinued operations:			
Income (loss) from discontinued operations before income taxes	1,727	341	(771)
Gain on disposition	145,982	—	—
Income tax expense	(39,435)	—	—
Income (loss) from discontinued operations	108,274	341	(771)
Net income (loss)	$120,779	$(32,885)	$(22,349)

Net income (loss) per ordinary share—basic:

Income (loss) from continuing operations	$0.48	$(1.40)	$(0.97)
Income (loss) from discontinued operations	4.17	0.01	(0.03)
Net income (loss)	$4.65	$(1.38)	$(1.00)
Net income (loss) per ordinary share—diluted:			
Income (loss) from continuing operations	$0.47	$(1.40)	$(0.97)
Income (loss) from discontinued operations	4.10	0.01	(0.03)
Net income (loss)	$4.58	$(1.38)	$(1.00)
Weighted-average shares used to compute net income (loss) per ordinary share—basic	25,982,809	23,757,902	22,353,713
Weighted-average shares used to compute net income (loss) per ordinary share—diluted	26,397,875	23,757,902	22,353,713

See accompanying notes to these consolidated financial statements.

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Oxford Immunotec Global PLC

Consolidated statements of other comprehensive income (loss)

(in thousands)

	Year ended December 31,		
	2018	**2017**	**2016**
Net income (loss)	$120,779	$(32,885)	$(22,349)
Other comprehensive gain (loss), net of taxes:			
Foreign currency translation adjustment, net of tax charges / (credits) of $791, $(1,178), and $0, respectively	(2,811)	2,039	(2,474)
Other comprehensive gain (loss), net of taxes	(2,811)	2,039	(2,474)
Total comprehensive income (loss)	$117,968	$(30,846)	$(24,823)

See accompanying notes to these consolidated financial statements.

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Oxford Immunotec Global PLC

Consolidated statements of shareholders' equity

(in thousands)

	Ordinary shares	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive gain (loss)	Total shareholders' equity
Balance at December 31, 2015	243	244,033	(146,307)	(5,277)	92,692
Exercise of share options	—	76	—	—	76
Share-based compensation expense	—	5,019	—	—	5,019
Other comprehensive loss	—	—	—	(2,474)	(2,474)
Net loss	—	—	(22,349)	—	(22,349)
Balance at December 31, 2016	243	249,128	(168,656)	(7,751)	72,964
Exercise of share options	4	557	—	—	561
Issuance of shares in secondary offering	22	39,276	—	—	39,298
Share-based compensation expense	—	5,864	—	—	5,864
Tax on vesting of restricted share units	—	(212)	—	—	(212)
Other comprehensive gain	—	—	—	2,039	2,039
Net loss	—	—	(32,885)	—	(32,885)
Balance at December 31, 2017	269	294,613	(201,541)	(5,712)	87,629
Exercise of share options	7	3,234	—	—	3,241
Share-based compensation expense	—	5,551	—	—	5,551
Tax on vesting of restricted share units	—	(383)	—	—	(383)
Other comprehensive loss	—	—	—	(2,811)	(2,811)
Net income	—	—	120,779	—	120,779
Balance at December 31, 2018	$ 276	$ 303,015	$ (80,762)	$ (8,523)	$ 214,006

See accompanying notes to these consolidated financial statements.

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Oxford Immunotec Global PLC

Consolidated statements of cash flows

(in thousands)

	Year ended December 31,		
	2018	**2017**	**2016**
Cash flows from operating activities			
Net income (loss)	$120,779	$(32,885)	$(22,349)
Less: Net income (loss) from discontinued operations, net of tax	108,274	341	(771)
Net income (loss) from continuing operations	12,505	(33,226)	(21,578)
Adjustments to reconcile net income (loss) from continuing operations to net cash used in operating activities:			
Depreciation and amortization of intangible assets	1,662	1,618	932
Change in fair value of contingent purchase price consideration	—	(3,475)	(1,208)
Intangible assets impairment charges	879	18,300	1,765
Accretion and amortization of loan fees	2,408	569	—
Share-based compensation expense	4,507	5,671	4,901
Loss (income) on disposal of property and equipment	115	298	—
Deferred income taxes	(38,760)	1,602	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(3,390)	(988)	(1,642)
Inventory, net	(1,015)	(1,768)	(1,486)
Prepaid expenses and other assets	207	(454)	(3,063)
Accounts payable	(10,375)	(5,502)	(7,326)
Accrued liabilities	3,252	509	3,069
Other liabilities, net	(4,209)	3,733	(36)
Deferred income	95	(9)	(1,639)
Net cash used in operating activities from continuing operations	(32,119)	(13,122)	(27,311)
Cash flows from investing activities			
Purchases of property and equipment	(5,350)	(1,295)	(856)
Cash paid for acquisitions, net of cash acquired	—	—	(27,515)
Net cash used in investing activities from continuing operations	(5,350)	(1,295)	(28,371)
Cash flows from financing activities			
Proceeds from issuance of ordinary shares	—	39,298	—
Proceeds from exercise of share options	3,241	561	76
Payments of tax withheld on vesting of restricted share units	(383)	(212)	—
Payments on capital lease	(60)	(261)	(80)
Proceeds from term loan, net	—	—	29,457

Discount on the line of credit	—	—	(50)
Debt issuance costs	—	—	(289)
Loss on extinguishment of debt	(2,105)	—	—
Change in loans payable	(30,000)	—	—
Net cash (used in) provided by financing activities from continuing operations	(29,307)	39,386	29,114
Net cash flows of continuing operations	(66,776)	24,969	(26,568)
Cash flows from discontinued operations			
Net operating cash flows provided by discontinued operations	14,729	9,548	5,401
Net investing cash flows provided by (used in) discontinued operations	156,218	(3,734)	(1,527)
Net financing cash flows used in discontinued operations	(48)	(12)	(11)
Net cash flows of discontinued operations	170,899	5,802	3,863
Effect of exchange rate changes on cash and cash equivalents, including restricted cash	(1,711)	451	(1,780)
Net increase (decrease) in cash and cash equivalents, including restricted cash	102,412	31,222	(24,485)
Cash, cash equivalents, and restricted cash at beginning of year	90,532	59,310	83,795
Cash, cash equivalents, and restricted cash at end of year	$192,944	$90,532	$59,310

See accompanying notes to these consolidated financial statements.

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Oxford Immunotec Global PLC

Consolidated statements of cash flows (continued)

(in thousands)

	Year ended December 31,		
	2018	**2017**	**2016**
Supplemental disclosures			
Cash paid for interest	$2,656	$3,123	$450
Cash paid for taxes	76	145	141

See accompanying notes to these consolidated financial statements.

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Oxford Immunotec Global PLC

Notes to consolidated financial statements

1. Description of business and significant accounting policies

Description of business

The Company is a global, high-growth diagnostics company focused on developing and commercializing proprietary tests for immunology and infectious disease by leveraging the technological, product development, manufacturing, quality, regulatory, and sales and marketing capabilities it has developed over its sixteen year history. The Company's proprietary T-SPOT.*TB* test utilizes its T-SPOT technology platform to test for tuberculosis, which is the leading cause of infectious disease death worldwide.

On November 6, 2018, the Company completed the sale of its U.S. Laboratory Services Business to Quest, for gross proceeds of $170 million in cash. This Transaction represented a strategic business shift and it had a major effect on the Company's operations and financial results. Following the Transaction, the Company has approximately 210 employees, including sales and marketing teams on three continents, and a laboratory in the United Kingdom.

Discontinued operations

The Company reports the results of operations of a business that either has been disposed of or is classified as held for sale, in accordance with Accounting Standards Codification, or ASC, 360, *Property, Plant, and Equipment*, in discontinued operations, as required by ASC 205, *Presentation of Financial Statements*. The Company presents such events as discontinued operations so long as the financial results can be clearly identified and the future operations and cash flows are completely eliminated from ongoing operations. The Company's historical results for all periods presented are restated to account for businesses reported as discontinued operations in our Consolidated Financial Statements and these Notes. Unless otherwise specified, disclosures in our Consolidated Financial Statements and these Notes relate solely to our continuing operations.

As discussed in Note 19, *Discontinued operations*, on September 25, 2018, the Company entered into an agreement to sell the Company's U.S. Laboratory Services Business to Quest Diagnostics Incorporated. The Transaction represents a strategic business shift having a major effect on the Company's operations and financial results. Accordingly, the assets and liabilities of this and the related operations have been reported in discontinued operations in the consolidated financial statements for all periods presented. The Transaction was consummated on November 6, 2018.

Basis of presentation, accounting principles and principles of consolidation

The accompanying consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America, or U.S. GAAP, and include the financial statements of Oxford Immunotec Global PLC, a company incorporated in England and Wales and its wholly-owned subsidiaries, collectively referred to as the Company. All intercompany accounts and transactions have been eliminated upon consolidation.

Segment reporting

The Company operates in one operating segment. The Company's chief operating decision maker, or the CODM, its chief executive officer, manages the Company's operations on an integrated basis for the purposes of allocating resources. When evaluating the Company's financial performance, the CODM reviews separate revenue information for the Company's product and service offerings and for each country, while all other financial information is on a consolidated basis. While the Company's principal operations and decision-making functions are located in both the United States and United Kingdom, the CODM makes decisions on a global basis. Accordingly, the Company has determined that it operates in a single reporting segment.

Use of estimates

The preparation of 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 at the date of the consolidated financial statements and that affect the reported amounts of revenue and expenditures during the reporting periods. Actual results could differ from those estimates and assumptions used.

Foreign currency translation

The functional currency for Oxford Immunotec Global PLC is the U.S. Dollar. The functional currency for the Company's operating subsidiaries are the Pound Sterling for Oxford Immunotec Limited, the U.S. Dollar for Oxford Immunotec USA, Inc., Oxford Immunotec Inc. and Immunetics, Inc., or Immunetics, the Yen for Oxford Immunotec K.K., the Yuan for Oxford Immunotec (Shanghai) Medical Device Co. Ltd., the Euro for Boulder Diagnostics Europe GmbH and the Hong Kong Dollar for Oxford Immunotec Asia Limited. Revenue and expenses of foreign operations are translated into U.S. Dollars at the average rates of exchange during the year. Assets and liabilities of foreign operations are translated into U.S. Dollars at year-end rates. The Company reflects resulting foreign currency translation adjustments in accumulated other comprehensive income, which is a component of shareholders' equity.

Realized and unrealized foreign currency transaction gains or losses, arising from exchange rate fluctuations on balances denominated in currencies other than the functional currencies, are included in "Other income (expense)" in the consolidated statements of operations unless the unrealized foreign currency transaction gains or losses relate to intercompany transactions of a long-term investment nature, then they are included in other comprehensive income.

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Concentration of risks

In the year ended December 31, 2018, the Company had two product customers that represented more than 10% of the Company's annual revenue. The Company's Chinese distributor, Shanghai Fosun Long March Medical Science Co. Ltd., or Fosun, represented approximately 27% of annual revenue and the Company's Japanese importer, Riken Genesis Co., Ltd. represented approximately 19% of annual revenue. The loss of either of these product customers could have a material impact on the Company's operating results.

Cash and cash equivalents and restricted cash

The Company considers all highly liquid investments purchased with maturities at acquisition of three months or less to be cash equivalents. The Company maintains its available cash balances in cash, money market funds and repurchase agreements primarily invested in U.S. government and agency securities, and bank savings accounts in the United States, United Kingdom, Germany, Japan, China and South Korea. The Company maintains deposits in government insured financial institutions in excess of government insured limits. Management believes that the Company is not exposed to significant credit risk due to the financial position of the depository institutions in which those deposits are held.

Restricted cash relates to collateral for procurement cards issued by a U.S. commercial bank.

Cash, cash equivalents, and restricted cash consists of the following:

	Year ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
Cash and cash equivalents	$192,844	$90,332	$59,110
Restricted cash, non-current	100	200	200
Total cash, cash equivalents, and restricted cash shown in the statement of cash flows	$192,944	$90,532	$59,310

Accounts receivable

Accounts receivable are primarily amounts due from customers including hospitals, public health departments, commercial testing laboratories, distributors and universities in addition to government programs.

Accounts receivable are reported net of an allowance for uncollectible accounts. The process of estimating the collection of accounts receivable involves significant assumptions and judgments. Specifically, the accounts receivable allowance is based on management's analysis of current and past due accounts, collection experience and other relevant information. The Company's provision for uncollectible accounts is recorded as a bad debt expense and included in general and administrative expenses. Account balances are written-off against the allowance when it is probable that the receivable will not be recovered. Although the Company believes amounts provided are adequate, the ultimate amounts of uncollectible accounts receivable could be in excess of the amounts provided.

Inventory

Inventory consists of raw materials, work in progress and finished goods. The Company does not maintain work in progress balances as the nature of the manufacturing process does not allow for test kits to be left in a partially manufactured state. Inventory is removed at cost. Inventory is stated at the lower of cost or net realizable value. Cost is determined by the actual cost of components by batch plus estimated labor and overhead costs per unit. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The Company reviews the components of its inventory on a periodic basis for excess, obsolete or impaired inventory, and records a reserve for identified items.

Property and equipment

Property and equipment are stated at cost. Property and equipment financed under capital leases are initially recorded at the present value of minimum lease payments at the inception of the lease.

Depreciation is calculated using the straight-line method over the estimated useful lives of the assets. Property and equipment under capital leases and leasehold improvements are amortized using the straight-line method over the shorter of the lease term or estimated useful life of the asset. Depreciable lives range from three to ten years for laboratory equipment, office equipment and furniture and fixtures and three years for software.

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Revenue recognition

The Company's revenues include product and service revenues. Product revenue from diagnostic test kit sales and related accessories is recognized at a point in time based upon contractual rates. Service revenue is recorded based upon contractually established billing rates and recognized upon delivery of test results to the customer. See Note 2 for disaggregation of revenue by type, indication and geography.

As of December 31, 2018, accounts receivables related to products and services were $9.2 million. For the year ended December 31, 2018, the Company had no material bad-debt expense and there were no material contract assets, contract liabilities or deferred contract costs recorded on the Consolidated Balance Sheet as of December 31, 2018. The Company generally expenses sales commissions when incurred because the amortization period would be less than one year.

Revenue expected to be recognized in any future year related to remaining performance obligations is not material.

Taxes assessed by governmental authorities on revenue, including sales and value added taxes, are recorded on a net basis (excluded from revenue) in the consolidated statements of operations.

Cost of revenue: cost of product and cost of service

Cost of product revenue consists primarily of costs incurred in the production process, including costs of raw materials and components, assembly labor and overhead, quality management, royalties paid under licensing agreements and packaging and delivery costs.

Cost of service revenue consists primarily of costs incurred in the operation of the Company's diagnostic laboratory including labor and overhead, kit costs, quality management, consumables used in the testing process and packaging and delivery costs.

Shipping and handling

The Company generally bills product customers for shipping and handling and records the customer payments as product revenue. The associated costs are recorded as cost of product sold.

The Company does not normally bill its service customers for shipping and handling charges. Charges relating to inbound and outbound freight costs are normally incurred by the Company and recorded within cost of service.

Impairment of long-lived assets

The Company's long-lived assets, including fixed assets and intangible assets which have a definite life, are evaluated for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may be impaired, and assesses their recoverability based upon anticipated future cash flows. If changes in circumstances lead the Company to believe that any of its long-lived assets may be impaired, the Company will (a) evaluate the extent to which the remaining book value of the asset (group) is recoverable by comparing the estimated undiscounted future cash flows attributable to the asset (group) in question to its carrying amount and (b) write-down the carrying amount to fair value to the extent necessary.

Business combinations

For acquisitions meeting the definition of a business combination, the Company allocates the purchase price, including any contingent consideration, to the assets acquired and the liabilities assumed at their estimated fair values as of the date of the acquisition with any excess of the purchase price paid over the estimated fair value of net assets acquired recorded as goodwill.

When determining the fair value of tangible assets acquired, the Company estimates the cost using the most appropriate valuation method with assistance from independent third-party specialists. When determining the fair value of intangible assets acquired, the Company uses judgment to estimate the applicable discount rate, growth rates and the timing and amount of future cash flows. The fair value of assets acquired and liabilities assumed is typically determined by management using the assistance of independent third-party specialists. The assumptions used in calculating the fair value of tangible and intangible assets represent the Company's best estimates. If factors changed and the Company were to use different assumptions, valuations of tangible and intangible assets and the resulting goodwill balance related to the business combination could be materially different.

Goodwill and indefinite-lived intangible assets

Goodwill

Goodwill is not amortized but is reviewed for impairment at least annually in the fourth quarter of the year, or when events or changes in the business environment indicate that all, or a portion, of the carrying value of the reporting unit may no longer be recoverable, using the two-step impairment review. Under this method, the Company compares the fair value of the goodwill to its carrying value. If the fair value is less than the carrying amount, a more detailed analysis is performed to determine if goodwill is impaired. An impairment loss, if any, is measured as the excess of the carrying value of goodwill over the fair value of goodwill. The Company also has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads it to determine that it is more likely than not (that is, a likelihood of more than 50%) that goodwill is impaired. If the Company chooses to first assess qualitative factors and determines that the fair value of the reporting unit more likely than not exceeded its carrying value, then it is not required to take further action to test goodwill for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which it may choose to do in some periods but not in others.

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Indefinite-lived intangible assets

Indefinite-lived intangible assets are reviewed for impairment at least annually, or when events or changes in the business environment indicate the carrying value may be impaired. If the fair value of the intangible asset is less than the carrying amount, the Company performs a quantitative test to determine the fair value. The impairment loss, if any, is measured as the excess of the carrying value of the intangible asset over its fair value. The Company also has the option to first assess qualitative factors to determine whether the existence of events or circumstances leads it to determine that it is more likely than not (that is, a likelihood of more than 50%) that its indefinite-lived intangible asset is impaired. If the Company chooses to first assess qualitative factors and determines that the fair value of the indefinite-lived intangible assets more likely than not exceeded their carrying value, then it is not required to test for impairment. The Company also has the option to bypass the qualitative assessment and perform only the quantitative impairment test, which it may choose to do in some periods but not in others.

The determinations as to whether, and, if so, the extent to which, indefinite-lived intangible assets become impaired are highly judgmental and based on significant assumptions regarding the projected future financial condition and operating results, changes in the manner of the use and development of the acquired assets, the Company’s overall business strategy, and regulatory, market and economic environment and trends.

Definite-lived intangible assets

Intangible assets include technology licenses which are capitalized and amortized over estimated useful lives (generally in the range of five to twenty years) using the straight-line method.

Derivative financial instruments

The Company does not use derivative instruments to hedge exposures to cash flow, market, interest rate or foreign currency risks.

The Company reviews the terms of the shares it issues to determine whether there are embedded derivative instruments, including embedded conversion options, which are required to be bifurcated and accounted for separately as derivative financial instruments. In circumstances where the host instrument contains more than one embedded derivative instrument, including the conversion option, that is required to be bifurcated, the bifurcated derivative

instruments are accounted for as a single, compound derivative instrument.

Bifurcated embedded derivatives are initially recorded at fair value and are then revalued at each reporting date with changes in the fair value reported as other income or expense. When equity instruments contain embedded derivative instruments that are to be bifurcated and accounted for as liabilities, the total proceeds received are first allocated to the fair value of all the bifurcated derivative instruments. The remaining proceeds, if any, are then allocated to the host instruments themselves, usually resulting in those instruments being recorded at a discount from their face value.

Fair value of financial instruments

The Company measures certain financial assets and liabilities at fair value based on the price that would be received for an asset or paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants. As of December 31, 2018 and 2017, the Company's financial instruments consist of cash and cash equivalents, accounts receivable, prepaid expenses, and other accounts payable, accrued liabilities, and loans payable. See Note 3. *Fair value measurement*, to the consolidated financial statements for further information on the fair value of the Company's financial instruments.

Research and development expenses

Research and development expenses include all costs associated with the development of the Company's technology platforms and potential future products including new diagnostic tests that utilize the Company's technology platforms and are charged to expense as incurred. Research and development expenses include direct costs and an allocation of indirect costs, including amortization, depreciation, rent, supplies, insurance and repairs and maintenance.

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Share-based compensation

The Company accounts for share-based compensation arrangements with employees, officers and directors by recognizing compensation expense based on the grant date fair value of share-based transactions in the consolidated financial statements.

Share-based compensation for options is based on the fair value of the underlying option calculated using the Black-Scholes option-pricing model on the date of grant for share options and recognized as expense on a straight-line basis over the requisite service period. Determining the appropriate fair value model and related assumptions requires judgment, including estimating share price volatility, expected term and forfeiture rates. The expected volatility rates are estimated based on the Company's actual volatility and the actual volatility of comparable public companies over a historical period equal in length to the expected term. The expected terms represent the average time that options are expected to be outstanding based on the midpoint between the vesting date and the end of the contractual term of the award. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. The Company has not paid dividends and does not anticipate paying cash dividends in the foreseeable future and, accordingly, uses an expected dividend yield of zero. The risk-free interest rate is based on the rate of U.S. Treasury securities with maturities consistent with the estimated expected term of the awards.

Certain employees have been granted restricted share units, or RSUs, and restricted shares. The fair value of RSUs and restricted shares are calculated based on the closing sale price of the Company's ordinary shares on the date of grant.

The cumulative expense recognized for share-based transactions at each reporting date until the vesting date reflects the extent to which the vesting period has expired and the Company's best estimate of the number of equity instruments that will ultimately vest. The charge or credit for a period represents the movement in cumulative expense recognized as of the beginning and end of that period. No expense is recognized for awards that do not ultimately vest.

Where the terms of an equity award are modified, the minimum expense recognized is the expense as if the terms had not been modified if the original terms of the award are met. An additional expense is recognized for any modification that increases the total fair value of the share-based compensation, or is otherwise beneficial to the employee as measured at the date of modification.

Where a share-based compensation award is cancelled, it is treated as if it had vested on the date of cancellation, and any expense not yet recognized for the award is recognized immediately. However, if a new award is substituted for the cancelled award, and designated as a replacement award on the date it is granted, the cancelled and new awards are

treated as if they were a modification of the original award, as described in the previous paragraph.

Upon exercise, share options are redeemed for newly issued ordinary shares.

Income taxes

The Company accounts for income taxes under the asset and liability method, which requires, among other things, that deferred income taxes be provided for temporary differences between the tax basis of the Company's assets and liabilities and its financial statement reported amounts. In addition, deferred tax assets are recorded for the future benefit of utilizing net operating losses and research and development credit carryforwards. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized.

The Company adheres to the accounting guidance for uncertainties in income taxes, which prescribes a recognition threshold and measurement process for recording in the financial statements uncertain tax positions taken, or expected to be taken, in a tax return. The Company accrues for the estimated amount of taxes for uncertain tax positions if it is more likely than not that the Company would be required to pay such additional taxes. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. Interest and penalties are recognized as a component of income tax expense.

Basic and diluted net income (loss) per ordinary share

Basic income (loss) per ordinary share are calculated by dividing the net income (loss) by the weighted-average number of ordinary shares outstanding during the period. Diluted income per ordinary share is calculated by dividing net income by the weighted-average number of ordinary shares outstanding during the period plus the dilutive effect of outstanding instruments such as share options, RSUs and restricted shares. Diluted loss per ordinary share is the same as basic loss per ordinary share, as the effect of utilizing the fully diluted share count including share options, RSUs and restricted shares would reduce the net loss per ordinary share.

Recently Adopted Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or FASB, issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09, which converges the FASB and the International Accounting Standards Board standards on revenue recognition. Under ASU 2014-09, a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In addition, ASU 2014-09

requires certain additional disclosures around the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The FASB has issued several amendments to the standard, including clarification on accounting for licenses of intellectual property, identifying performance obligations and other technical corrections. The Company adopted ASU 2014-09 on January 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material impact on the Company's financial position, results of operations, equity or cash flows as of the adoption date or for the year ended December 31, 2018. The Company has included the disclosures required by ASU 2014-09 above and in Note 2. *Revenue* to the Consolidated Financial Statements.

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In August 2016, the FASB issued ASU 2016-15, *Classification of Certain Cash Receipts and Cash Payments*, or ASU 2016-15. ASU 2016-15 is intended to reduce the diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The Company adopted ASU 2016-15 retrospectively as of January 1, 2018. The adoption of ASU 2016-15 has not had a material impact on the Company's statement of cash flows.

In October 2016, the FASB issued ASU 2016-16, *Income Taxes*, or ASU 2016-16. The guidance requires companies to recognize the income tax effects of intercompany sales and transfers of assets, other than inventory, in the income statement as income tax expense (or benefit) in the period in which the transfer occurs. The Company adopted ASU 2016-16 retrospectively as of January 1, 2018. The adoption of ASU 2016-16 has not had a material impact on the Company's financial position, results of operations or related disclosures.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, or ASU 2016-18. ASU 2016-18 requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. The Company adopted ASU 2016-18 retrospectively as of January 1, 2018. The adoption of ASU 2016-18 has not had a material impact on the Company's statement of cash flows.

In January 2017, the FASB issued ASU 2017-01, *Business Combinations*, or ASU 2017-01. ASU 2017-01 clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. The Company adopted ASU 2017-01 prospectively as of January 1, 2018. The adoption of ASU 2017-01 has not had a material impact on the Company's financial position, results of operations or related disclosures.

In May 2017, the FASB issued ASU 2017-09, *Scope of Modification Accounting*, or ASU 2017-09. ASU 2017-09 provides guidance about which changes to the terms or conditions of a share-based payment award require an entity to apply modification accounting of a share-based payment award. The guidance should be applied prospectively to an award modified on or after the adoption date. The Company adopted ASU 2017-09 prospectively as of January 1, 2018. The adoption of ASU 2017-09 has not had a material impact on the Company's financial position, results of operations or related disclosures.

Recently Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases*, or ASU 2016-02. ASU 2016-02 requires lessees to reflect all leases with terms longer than 12 months on their balance sheets. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. The FASB has

subsequently issued amendments to the guidance, including the addition of an optional transition method. The Company's process of evaluating the impact of ASU 2016-02 has included reviewing all forms of leases and performing a completeness assessment over the lease population. The Company will adopt ASU 2016-02, effective as of January 1, 2019 and will apply the alternative adoption approach at the adoption date and will recognize a cumulative-effect adjustment, if any, to the opening balance of retained earnings. The Company will take advantage of the transition package of practical expedients permitted within ASU 2016-02, which among other things, will allow it to carryforward historical lease classifications. The Company will make an accounting policy election that will keep leases with an initial term of 12 months or less and that do not include an option to purchase the underlying asset that the Company is reasonably certain to exercise off of the balance sheet and will result in recognizing those lease payments in the consolidated statements of operations on a straight-line basis over the lease term. As a result of adopting ASU 2016-02, the Company expects to recognize right-of-use assets of about $7.7 million and corresponding liabilities of about $8.6 million for its existing lease portfolio on its consolidated balance sheets, with no material impact to the Company's consolidated statements of operations or consolidated statements of cash flows. For the first quarter of 2019, the Company will provide additional disclosures in the notes to its condensed consolidated financial statements regarding its leasing portfolio, including key judgments and assumptions and the discount rates used in calculating the Company's right-of-use assets and corresponding liabilities.

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments-Credit Losses*, or ASU 2016-13. ASU 2016-13 requires a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. Under current U.S. GAAP, a company only considered past events and current conditions in measuring an incurred loss. Under ASU 2016-13, the information that a company must consider is broadened in developing an expected credit loss estimate for assets measured either collectively or individually. The use of forecasted information incorporates more timely information in the estimate of expected credit loss. The new guidance will be effective for the Company for annual and interim periods beginning after December 15, 2019. Early adoption is permitted for annual and interim periods beginning after December 15, 2018. The guidance is applied using a modified retrospective, or prospective approach, depending on a specific amendment. The Company does not expect that the application of ASU 2016-13 will have a material impact on the presentation of its results of operations, financial position or disclosures.

In January 2017, the FASB issued ASU 2017-04, *Intangibles – Goodwill and Other*, or ASU 2017-04. ASU 2017-04 simplifies subsequent measurement of goodwill by eliminating Step 2 from the goodwill impairment test. The new guidance will be applied on a prospective basis. ASU 2017-04 will be effective for the Company for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. Early adoption is permitted for interim or annual goodwill impairment tests. The Company is currently evaluating ASU 2017-04.

In June 2018, the FASB issued ASU 2018-07, *Improvements to Nonemployee Share-Based Payment Accounting*, or ASU 2018-07. ASU 2018-07 simplifies the accounting for share-based payments to nonemployees by aligning it with the accounting for share-based payments to employees, with certain exceptions. ASU 2018-07 will be effective for the Company for fiscal years beginning after December 15, 2018, including interim periods within that fiscal year. Early adoption is permitted. The Company is currently evaluating ASU 2018-07.

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2. Revenue

On January 1, 2018, we adopted FASB ASC Topic 606, *Revenue from Contracts with Customers,* or ASC Topic 606, under the modified retrospective approach using the practical expedient in paragraph 606-10-10-4. The five step model defined by ASC Topic 606 requires us to (1) identify our contracts with customers, (2) identify our performance obligations under those contracts, (3) determine the transaction prices of those contracts, (4) allocate the transaction prices to our performance obligations in those contracts and (5) recognize revenue when each performance obligation under those contracts is satisfied. Revenue is recognized when promised goods or services are transferred to the customer in an amount that reflects the consideration expected in exchange for those goods or services. Our adoption of ASC Topic 606 did not result in an adjustment to our accumulated deficit and did not have a material impact on the amount and timing of our revenue recognition for the year ended December 31, 2018.

The Company's prior year revenues have been recast to present the U.S. Laboratory Services Business as a discontinued operation. For further information on these changes, refer to Note 19. *Discontinued operations.*

The following tables present the Company's revenues disaggregated by type:

	Year ended December 31,		
(in thousands)	**2018**	**2017**	**2016**
Revenue			
Product	$54,687	$48,899	$43,070
Service	5,066	5,834	3,918
Total revenue	$59,753	$54,733	$46,988

The following tables reflect revenue by geography (United States, Europe and rest of world, or Europe and ROW, and Asia):

	Year ended December 31,					
(in thousands, except percentages)	**2018**		**2017**		**2016**	
Revenue						
United States	$16,442	28 %	$15,720	29 %	$10,372	22 %
Europe and ROW	9,153	15 %	8,136	15 %	6,988	15 %
Asia	34,158	57 %	30,877	56 %	29,628	63 %
Total revenue	$59,753	100%	$54,733	100%	$46,988	100%

3. Fair value measurement

As a basis for determining the fair value of certain of the Company's financial instruments, the Company utilizes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1—Observable inputs such as quoted prices in active markets for identical assets or liabilities.

Level 2—Observable inputs, other than Level 1 prices, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.

Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

This hierarchy requires the Company to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value. The carrying amount of certain of the Company's financial instruments, including cash, accounts receivable, prepaid expenses and other assets, accounts payable, and accrued liabilities approximate fair value due to their short term nature.

Assets and liabilities measured at fair value are classified in their entirety based on the lowest level of input that is significant to the fair value measurement. The Company's assessment of the significance of a particular input to the entire fair value measurement requires management to make judgments and consider factors specific to the asset or liability.

The Company had a term loan outstanding under an agreement with MidCap Financial Trust, or MidCap, at December 31, 2017. The amount outstanding on the term loan was reported at its carrying value in the accompanying balance sheet at that date. The estimated fair value of the term loan, based upon market rates at the time for similar borrowings, as measured using Level *2* inputs, approximated the carrying amount as presented on the consolidated balance sheets. In connection with the sale of the U.S. Laboratory Services Business to Quest on November 6, 2018, approximately $32.3 million of the gross proceeds received pursuant to the Transaction, was paid directly to MidCap to repay the outstanding indebtedness under the MidCap agreement, which included prepayment and exit fees of approximately $2.3 million (see *Note 9. Loans payable*).

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4. Accounts receivable, net

Accounts receivable, net, consisted of the following as of:

	December 31,	
(in thousands)	**2018**	**2017**
Accounts receivable	$9,246	$6,021
Less allowance for uncollectible accounts receivable	(88)	—
Accounts receivable, net	$9,158	$6,021

Activity for the allowance for uncollectible accounts receivable is as follows:

	December 31,		
(in thousands)	**2018**	**2017**	**2016**
Balance at beginning of period	$—	$—	$—
Provision for bad debt expense	(88)	—	—
Write-off	—	—	—
Balance at end of period	$(88)	$—	$—

5. Inventory, net

Inventory consisted of the following as of:

	December 31,	
(in thousands)	**2018**	**2017**
Raw materials	$6,169	$6,927
Work in progress	190	179
Finished goods	1,408	31
Inventory	$7,767	$7,137

6. Property and equipment, net

Property and equipment, net consists of the following as of:

	December 31,	
(in thousands)	**2018**	**2017**
Laboratory equipment	$2,951	$2,493
Leasehold improvements	5,663	2,766
Office equipment, furniture and fixtures	3,019	2,205
Software	1,626	756
Construction in progress	—	94
Property and equipment	13,259	8,314
Less accumulated depreciation	(6,115)	(5,550)
Property and equipment, net	$7,144	$2,764

For the years ended December 31, 2018, 2017 and 2016, the Company recorded depreciation expense of $1.6 million, $1.4 million and $0.9 million, respectively. Depreciation expense includes amortization of capital leases.

Depreciable lives range from three to ten years for laboratory equipment, office equipment, leasehold improvements, and furniture and fixtures and three years for software and specialized shipping containers.

For the years ended December 31, 2018 and 2017, there were no material capital leases, disposals or retirements.

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7. Goodwill and intangible assets

The Company has one reporting unit and goodwill represents the synergies realized in its acquisitions of Imugen, Inc., or Imugen, and Immunetics, Inc., or Immunetics. In conjunction with the Transaction (see Note 19. *Discontinued operations*) and pursuant to ASC 350-20-35-51, the Company allocated a portion of the goodwill to the business being disposed of based on the relative fair value method. As a result, goodwill of $1.5 million was allocated to assets held for sale in the third quarter of 2018, the period that the held for sale election was determined. The carrying amount of goodwill reflected in the Company's consolidated balance sheets was $2.5 million at December 31, 2018 and 2017.

Acquired intangible assets consisted of the following as of December 31, 2018 and 2017 (in thousands):

	As of December 31, 2018			
	Amortization period (years)	Gross carrying amount	Accumulated Amortization	Net carrying amount
Licenses	5-10	$ 652	$ 591	$ 61
Total		$ 652	$ 591	$ 61

	As of December 31, 2017			
	Amortization period (years)	Gross carrying amount	Accumulated Amortization	Net carrying amount
Immunetics technology – clinical	15	$ 883	$ 72	$ 811
Immunetics customer relationships	5-11	130	14	116
Immunetics trade name	5	30	8	22
Other	5-10	692	605	87
Total		$ 1,735	$ 699	$ 1,036

In conjunction with the Transaction, the net carrying amount of definite-lived intangible assets recorded in the acquisition of Imugen were disposed of and netted into the gain on sale.

The weighted average amortization period of our definite-lived intangible assets is 9.7 years. Amortization expense from continuing operations for the years ended December 31, 2018, 2017 and 2016 was $93,000, $206,000 and $71,000, respectively. Amortization expense related to acquired intangible assets is estimated at $22,000 per year for the years 2019 and 2020 and $17,000 in 2021.

The acquisition of Immunetics was accounted for under the acquisition method of accounting and the purchase price allocation was provisionally prepared during the fourth quarter of 2016. In the second quarter of 2017, the Company finalized the accounting for the acquisition and recorded the following measurement period adjustments:

- the fair value of the acquired inventory decreased by $45,000 with corresponding increases to the clinical technology asset of $22,500 and to goodwill of $22,500
- the fair value of the acquired customer relationships decreased by $50,000 with a corresponding increase to goodwill
- the fair value of the Immunetics trade name decreased by $130,000 with a corresponding increase to goodwill
- a $58,000 decrease to goodwill due to changes in income tax expense

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The impact on the consolidated statement of operations as of December 31, 2017 was a $44,000 reduction in cost of product revenue, a $26,000 reduction in sales and marketing expense and a $58,000 increase in income tax expense.

During the fourth quarter of 2016, the Company recorded a non-cash IPR&D impairment charge of $1.4 million related to an assay for Lyme disease that was acquired in conjunction with the Boulder acquisition when it was determined that the Boulder IPR&D will not directly yield any products.

In the third quarter of 2017, due to increased competition in the molecular blood donor screening market for *Babesia microti*, the Company recorded an impairment charge of $11.1 million to write-off certain intangible assets acquired in conjunction with the 2016 acquisition of Imugen including:

- $9.2 million related to Imugen IPR&D;
- $1.1 million related to customer relationships; and
- $701,000 related to the Imugen trade name.

In mid-February 2018, the Company received a complete response letter, or CRL, from FDA which raised a number of questions related to the Company's submissions in the fourth quarter of 2017 in support of licensure for the Immunetics *Babesia microti* blood donor screening assay. Given FDA's previous verbal comments to the Company, the CRL was unexpected and would have delayed licensure and commercialization of the assay. As a result, the Company recorded an impairment charge of $7.2 million to write off the intangible assets related to the assay including:

- $7.0 million related to Immunetics IPR&D;
- $166,000 related to the Immunetics trade name; and
- $98,000 related to customer relationships.

Impairment review

Immunetics definite-lived intangible assets

The Company reviews the carrying value of its long-lived assets, including other intangible assets, for impairment whenever events or changes in circumstances indicate that the carrying value of an asset or asset group may not be recoverable. The Company evaluates recoverability based upon undiscounted future cash flows expected to be

generated by such assets (group) over the remaining useful lives. On November 6, 2018, the Company sold its U.S. Laboratory Services Business to Quest pursuant to a Limited Liability Company Interest Purchase Agreement for approximately $170 million (See Note 19. *Discontinued operations).* Following this transaction, Management held strategic meetings that resulted in an impairment review of the assets group related to Immunetics. Upon impairment review, the Company recorded an impairment charge of $879,000 to write off the Immunetics intangible assets in the fourth quarter of 2018.

Goodwill

Goodwill is not amortized but is reviewed for impairment at least annually in the fourth quarter of the year, or when events or changes in the business environment indicate that all, or a portion, of the carrying value of the reporting unit may no longer be recoverable, using the two-step impairment review. Based on the results of the Company's annual review of goodwill, it has been determined that there is no impairment loss to be recorded in the fourth quarter of 2018.

8. Accrued liabilities

Accrued liabilities consist of the following as of:

	December 31,	
(in thousands)	**2018**	**2017**
Employee related expenses	$5,536	$4,317
Corporate tax	1,616	—
Royalties	1,354	1,419
Other accrued liabilities	2,385	2,071
Total accrued liabilities	$10,891	$7,807

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9. Loans payable

In June 2013, in conjunction with the lease for approximately 14,500 square feet of office space in Marlborough, Massachusetts, the Company received a payment of $582,000 from the landlord, representing approximately 80% of the cost to build-out the facility. In accordance with FASB Accounting Standards Codification 840, *Leases*, this reimbursement was recorded as a liability in loans payable and is being amortized over the life of the lease. At December 31, 2018, $84,000 is included in the balance sheet in current portion of loans payable and $75,000 is included in long-term portion of loans payable. At December 31, 2017, $77,000 is included in the balance sheet in current portion of loans payable and $159,000 is included in long-term portion of loans payable.

On October 4, 2016, the Company entered into an agreement with MidCap Financial Trust, or the MidCap agreement, that provided it with $40 million in debt financing, comprised of both a term loan and a revolving line of credit. The MidCap agreement provided the Company with a term loan of $30 million, which matured five years from closing. The term loan accrued interest at a rate of LIBOR plus 7.60% with interest only payments for the first 24 months, with the ability to extend to 48 months subject to certain conditions, before the loan began to amortize. The MidCap agreement also provided the Company with a revolving line of credit of up to $10 million, which matured five years from closing. The revolving line of credit accrued interest at a rate of LIBOR plus 4.45%. The Company was also required to pay the lenders an unused line fee equal to 0.50% per annum of the average unused portion of the revolving line of credit. Based on certain conditions, both the term loan and revolving line of credit could have been increased by an additional $10 million for a total of $60 million.

If the credit facility was terminated prior to the end of the term, the Company was to pay to the lenders a fee as compensation for the costs of being prepared to make funds available to the Company throughout the term equal to an amount determined by multiplying the revolving line of credit commitment amount by 3.0% in the first year, 2.0% in the second year, and 1.0% in the third year and thereafter. Upon repayment in full of the loan, the Company was obligated to make a final payment fee equal to 6% of the aggregate loan amount. In addition, the Company was required to pay an exit fee of 6.0% of the aggregate principal amount of all term loan borrowings. The 6% exit fee was being accreted to interest expense through the maturity of the Midcap loan.

In connection with the sale of the U.S. Laboratory Services Business to Quest pursuant to a Limited Liability Company Interest Purchase Agreement on November 6, 2018, approximately $32.3 million of the gross proceeds received pursuant to the Transaction was paid directly to MidCap to repay the outstanding indebtedness under the MidCap agreement, which included prepayment and exit fees of approximately $2.3 million. In connection with the Company’s repayment of the outstanding indebtedness under the MidCap Agreements, the Term Loan and the Revolving Loan, and all related agreements thereunder, were terminated and all borrowings outstanding thereunder were repaid in full. The repayment resulted in a loss on extinguishment of debt of $2.1 million, which represents the cash paid to settle the debt in excess of debt related balances at the time of settlement.

As of December 31, 2017, the Company had a balance of the secured term loan due to MidCap of $30 million, which is recorded in the accompanying consolidated balance sheet at that date, net of unamortized discount and debt issuance costs.

The Company never borrowed under the revolving line of credit.

10. Share capital

During the twelve months ended 2018, the Company issued 694,322 ordinary shares upon the exercise of options and 83,378 ordinary shares were issued upon the vesting of RSUs. During 2017, 500,182 ordinary shares were issued upon the exercise of options, and 26,021 ordinary shares were issued upon the vesting of RSUs. There were 36,183,293 ordinary shares authorized, and 26,439,334 and 25,661,634 ordinary shares issued and outstanding, as of December 31, 2018 and 2017, respectively.

On August 14, 2017, the Company entered into an underwriting agreement, or the Underwriting Agreement, with BTIG, LLC, as sole underwriter, relating to the issuance and sale of 2,500,000 ordinary shares, nominal value £0.006705 per share, at a price to the public of $16.05 per share, or the Offering, which resulted in approximately $39.3 million of net proceeds to the Company after deducting underwriting discounts and estimated offering expenses. The Offering closed on August 18, 2017.

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11. Share option and equity incentive plans

The Company has issued share options since 2003, restricted shares since 2014 and RSUs since 2015 to incentivize employees and directors providing services to the Company. Currently, the Company maintains two equity compensation plans, the Amended and Restated 2008 Stock Incentive Plan and the 2013 Share Incentive Plan, or the Plans. With the adoption of the 2013 Share Incentive Plan or the 2013 Plan, the Company is no longer authorized to grant awards under the Amended and Restated 2008 Stock Incentive Plan.

In November 2013, in connection with the Company's IPO, the Company adopted the 2013 Plan, which provides for the grant of share options, restricted shares, RSUs and other share-based awards to employees, officers, directors and consultants of the Company. The 2013 Plan authorized the Company to grant up to 2,684,563 ordinary shares with such amount automatically increasing annually on each January 1st through January 1, 2023 by 4% of the number of shares outstanding on the close of business of the immediately preceding December 31st, provided that the Board of Directors may limit the increase to a smaller amount or to no increase in any given year. The 2013 Plan was amended in April 2017 to delete the provision that allows for yearly increases to the shares available for issuance under the Plan. At that time, the maximum number of shares available for future issuance was also capped at 2,684,563, which is the original amount of shares allocated for issuance under the 2013 Plan. At December 31, 2018, there were 1,712,132 shares available for future issuance under the 2013 Plan.

Under both the 2008 Plan and the 2013 Plan, share options, and only under the 2013 Plan, restricted shares and RSUs, have been granted to employees, officers and directors who provide services to the Company. Options generally vest based on the grantee's continued service with the Company during a specified period following grant or, in rare instances, based on the achievement of performance or other conditions as determined by the Board of Directors, and expire after ten years. For options granted prior to 2015, the vesting percentage was generally 0% until the second anniversary of the vesting start date of the employee's first option award under the 2008 Plan and either the second anniversary of the employee's date of hire or the first day of the month following the second anniversary of the employee's date of hire under the 2013 Plan. Effective in 2015, the Company began granting options that vest in equal parts over four years starting on the vesting start date. Generally, restricted shares and RSUs vest based on the grantees' continued service with the Company during a specified period following grant as follows: 40% on the second anniversary of the grant date; 30% on the third anniversary of the grant date; and 30% on the fourth anniversary of the grant date.

The fair value of the options was estimated at the grant date using the Black-Scholes option pricing model, taking into account the terms and conditions upon which options are granted. The fair value of the options is amortized on a straight-line basis over the requisite service period of the awards. The weighted-average grant date fair value per share relating to share options granted under the Plans during the years ended December 31, 2018, 2017 and 2016 was $6.15, $6.31 and $4.53, respectively. Share-based compensation expense for restricted shares and RSUs is calculated based on the grant date market price of the shares and is also amortized on a straight-line basis over the requisite service period of the awards.

The fair value of each option granted under the Plans has been calculated on the date of grant using the following assumptions:

	2018	2017	2016
Expected dividend yield (%)	—	—	—
Expected volatility (%)	43.70	43.59	43.70
Risk-free interest rate (%)	2.70	1.98	1.53
Expected life of option (years)	6.25	6.20	6.16
Weighted-average share price ($)	13.37	14.06	10.29
Weighted-average exercise price ($)	4.67	14.06	10.29
Model used	Black-Scholes Model	Black-Scholes Model	Black-Scholes Model

Expected dividend yield: The Company has not paid and does not anticipate paying any dividends in the foreseeable future.

Expected volatility: As the Company operated as a private company until November 2013, there is not sufficient historical volatility for the expected term of the options. Therefore, in the first half of the year, the Company used 75% of average share price volatility of the peer group companies and 25% of its own average share price volatility. In the second half of the year, the Company used 50% of average share price volatility of the peer group companies and 50% of its own average share price volatility. The Company intends to increase the weighting of its own historical share price volatility in its volatility factor calculation by 25% each year until a sufficient amount of historical information regarding the volatility of its own share price becomes available.

Risk-free interest rate: The Company determined the risk-free interest rate by using a weighted-average equivalent to the expected term based on the U.S. Treasury yield curve in effect as of the date of grant.

Expected life of options (in years): Expected life of options represents the period that the Company’s share option grants are expected to be outstanding. As the Company operated as a private company until November 2013, there is not sufficient historical share data to calculate the expected term of the options. Therefore, the Company elected to utilize the “simplified” method to value share option grants. Under this approach, the weighted-average expected life is presumed to be the average of the vesting term and the contractual term of the option.

Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from estimates. The Company estimates forfeitures based on historical termination behavior. For the years ended December 31, 2018, 2017 and 2016, forfeiture rates of 5% were applied to both management and non-management grants.

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The following table illustrates the number of ordinary shares and weighted-average exercise prices, or WAEP, of, and movements in, share options during the year:

	Number of ordinary shares	WAEP
Outstanding as of January 1, 2018	3,104,613	$11.62
Granted	796,264	13.37
Exercised	(694,322)	4.67
Forfeited	(643,386)	14.31
Outstanding as of December 31, 2018	2,563,169	13.37
Vested or expected to vest as of December 31, 2018	2,494,307	$13.37
Exercisable as of December 31, 2018	1,401,639	$13.47

The following table illustrates the number of restricted shares and RSUs, and weighted-average fair value, or WAFV, of, and movements in, restricted shares and RSUs during the year:

	Number of ordinary shares	WAFV
Unvested balance as of January 1, 2018	418,518	$14.93
Granted	166,008	13.37
Cancelled	(112,694)	13.09
Vested	(170,878)	16.98
Unvested balance as of December 31, 2018	300,954	13.88

As of December 31, 2018, there was $5.2 million and $3.0 million of total unrecognized compensation cost related to unvested share options and unvested restricted shares and RSUs, respectively, granted under the Plans. The cost for unvested share options and unvested restricted shares and RSUs is expected to be recognized over weighted-average periods of 2.4 years and 2.6 years, respectively.

The aggregate intrinsic value of all share options outstanding under the Plans as of December 31, 2018 and 2017 was $2.8 million and $10.7 million, respectively. The aggregate intrinsic value of share options that were exercisable under the Plans as of December 31, 2018 and 2017 was $2.4 million and $8.8 million, respectively.

During the years ended December 31, 2018, 2017 and 2016, current and former employees of the Company exercised a total of 694,322, 500,182 and 85,943 share options, respectively, resulting in total proceeds of $3.2 million during 2018, $561,000 during 2017 and $76,000 during 2016. The intrinsic value of share options exercised during the years ended December 31, 2018, 2017 and 2016 was $6.7 million, $7.2 million and $1.0 million, respectively. In accordance with Company policy, the shares were issued from a pool of shares reserved for issuance under the Plans described above.

A summary of the activity of the Company's unvested share options is as follows:

	Number of shares	Weighted-average grant date fair value
Balance as of December 31, 2017	1,479,293	$ 5.83
Granted	796,264	6.15
Vested	(651,787)	5.59
Forfeited	(462,240)	6.56
Balance as of December 31, 2018	1,161,530	6.06

The total fair value of shares vested for the years ended December 31, 2018, 2017 and 2016 was $3.7 million, $3.1 million and $2.9 million, respectively.

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The impact on the Company's results of continuing and discontinued operations from share-based compensation for the years ended December 31, 2018, 2017 and 2016, was as follows:

(in thousands)	2018	2017	2016
Cost of revenue	$182	$168	$52
Research and development	758	654	497
Sales and marketing	965	1,844	1,671
General and administrative	2,602	3,005	2,681
Total continuing operations	4,507	5,671	4,901
Discontinued operations	1,044	193	118
Total share-based compensation	$5,551	$5,864	$5,019

On September 10, 2018, the Company's Board of Directors approved the modification of unvested equity awards awarded to approximately 35 employees expected to move to Quest. Per the terms of the modification, upon closing of the transaction, all outstanding awards became fully vested. The Company accounted for the modification as of September 25, 2018, when the Company signed the Purchase Agreement with Quest and the performance criteria became probable. At that time, all expense related to unvested awards was reversed, and the modified awards were revalued. The Company compared the fair value of the award immediately before and after the modification, and there was no incremental compensation to be recognized. Expense related to the modified awards was fully recognized on the closing date. Approximately 120,000 options and 28,100 RSUs were accelerated.

For the year ended December 31, 2018, the Company incurred shared-based compensation expense related to share options and restricted shares and RSUs of approximately $3.6 million and $2.0 million, respectively. For the year ended December 31, 2017, the Company incurred shared-based compensation expense related to share options, and restricted shares and RSUs of approximately $3.6 million and $2.2 million, respectively. For the year ended December 31, 2016, the Company incurred shared-based compensation expense related to share options and restricted shares of approximately $3.2 million and $1.8 million, respectively.

12. Net income (loss) per ordinary share

The following table provides a reconciliation of the numerator and denominator used in computing basic and diluted net income (loss) per share:

Year ended December 31,

($ in thousands)	2018	2017	2016
Numerator:			
Income (loss) from continuing operations	$12,505	$(33,226)	$(21,578)
Income (loss) from discontinued operations	108,274	341	(771)
Net income (loss)	$120,779	$(32,885)	$(22,349)
Denominator:			
Weighted-average ordinary shares outstanding-basic	25,982,809	23,757,902	22,353,713
Dilutive effect of ordinary share equivalents resulting from ordinary share options, unvested restricted shares and RSUs	415,066	—	—
Weighted-average ordinary shares outstanding-diluted	26,397,875	23,757,902	22,353,713

The following numbers of outstanding ordinary share options, restricted shares and RSUs were excluded from the computation of diluted net loss per share for the periods with a net loss because their effect would have been anti-dilutive:

	Year ended December 31,		
	2018	2017	2016
Options to purchase ordinary shares	—	878,242	1,065,655
Unvested restricted shares and RSUs	—	418,518	329,465

13. Income taxes

The components of loss from continuing operations before income taxes are as follows for the years ended December 31:

(in thousands)	2018	2017	2016
Domestic (United Kingdom)	$12,623	$18,171	$(730)
Foreign (United States)	(37,404)	(49,763)	(24,622)
Loss from continuing operations before income taxes	$(24,781)	$(31,592)	$(25,352)

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The components for the income tax (expense) benefit from continuing operations are as follows for the years ended December 31:

(in thousands)	2018	2017	2016
Current:			
Federal	$—	$—	$—
U.K.	(532)	—	—
Japan	(45)	(14)	(85)
China	(13)	(39)	(12)
State	—	(46)	(51)
Total current provision	(590)	(99)	(148)
Deferred:			
Federal	30,665	—	752
U.K.	(1,343)	(1,535)	2,630
State	8,554	—	540
Total deferred benefit (expense)	37,876	(1,535)	3,922
Income tax benefit (expense)	$37,286	$(1,634)	$3,774

Intraperiod tax allocation rules require the Company to allocate the provision for income taxes between continuing operations and other categories of earnings, such as discontinued operations and other comprehensive income. In periods in which the Company has a year-to-date pre-tax loss from continuing operations and pre-tax income in other categories of earnings, such as discontinued operations, we must allocate the tax provision to the other categories of earnings. As a result, the Company has recorded a tax expense of approximately $39.4 million in discontinued operations related to the sale of the Company's U.S. Laboratory Services Business to Quest. A corresponding tax benefit has been recorded as part of continuing operations, representing the valuation allowance released on the beginning of the year net operating losses.

The Company's effective income tax rate differs from the statutory domestic (United Kingdom) income tax rate as follows for the years ended December 31:

	2018	2017	2016
Income tax rate	19.0 %	19.3 %	20.0 %
U.K. research and development credit	1.8	1.5	1.9
Effect of U.S. tax reform – Federal tax rate change	—	(69.2)	—
Permanent items	1.0	5.9	(1.9)
Prior period adjustments	(5.2)	—	—
State taxes	9.2	9.6	4.9
Other	2.0	4.6	(1.5)
Effect of foreign tax rate differential	2.9	28.0	13.1
Uncertain tax positions	(1.7)	—	—
Valuation allowance	121.5	(5.0)	(21.6)

Effective income tax rate	150.5%	(5.3)%	14.9%

The Company is headquartered in the United Kingdom and the statutory U.K. corporate tax rate for the years ended December 31, 2018, 2017 and 2016 was 19.0%, 19.3% and 20.0%, respectively. The U.S. federal corporate tax rate for the years ended December 31, 2018, 2017 and 2016 was 21%, 34% and 34%, respectively. The Company is subject to taxation in the U.S. and various state, local and foreign jurisdictions. The Company remains subject to examination by various tax authorities for tax years 2015 through 2018. With a few exceptions, the Company is no longer subject to examinations by tax authorities for the tax years 2014 and prior. However, net operating losses from the tax years 2014 and prior would be subject to examination if and when used in a future tax return to offset taxable income. The Company's policy is to recognize income tax related penalties and interest, if any, in its provision for income taxes and, to the extent applicable, in the corresponding income tax assets and liabilities, including any amounts for uncertain tax positions.

The United Kingdom's Summer Finance Bill, which was enacted on September 15, 2016, contained reductions in corporation tax to 19% from April 1, 2017 and 17% from April 1, 2020. The Company has measured its U.K. deferred taxes at the statutory tax rate of 17%, reflecting the anticipated timing of the reversal of its deferred tax balances.

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Deferred income taxes reflect the net tax effect of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's deferred tax assets and deferred tax liabilities are as follows for the years ended December 31:

(in thousands)	**2018**	**2017**
Deferred tax assets:		
U.S. federal net operating losses	$11,478	$33,713
State net operating loss (net of federal)	2,865	8,450
U.S. federal research and development credit	849	587
U.K. net operating loss	496	1,894
Share options	1,724	2,611
Accrued liabilities	1,052	393
Intangible assets	—	2,392
State credits	512	377
Other	136	167
Total deferred tax assets	19,112	50,584
Valuation allowance	(17,991)	(48,098)
Total deferred tax assets	$1,121	$2,486
Deferred tax liabilities:		
Other assets	$(69)	$—
Total deferred tax liabilities	$(69)	$—

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the TCJA, was enacted. This tax reform legislation makes significant changes in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the current rate of 34% to 21% effective on January 1, 2018. As a result of the enacted law, the Company was required to revalue deferred tax assets and liabilities at the 21% rate. This resulted in a decrease in the company's net deferred tax asset and corresponding valuation allowance of $21.4 million. As the Company maintained a full valuation allowance against its net deferred tax asset position in the United States, this revaluation did not result in an income tax expense or benefit in the prior period. The other provisions of the TCJA did not have a material impact on the 2017 or 2018 consolidated financial statements.

For the years ended December 31, 2018 and 2017, the Company had United Kingdom Net Operating Losses (U.K. NOLs) of $2.9 million and $11.1 million, respectively. U.S. federal net operating loss carry forwards for the years ended December 31, 2018 and 2017 were $54.7 million and $160.5 million, respectively. U.S. State net operating loss carryforwards for the years ended December 31, 2018 and 2017 were $50.3 million and $154.9 million, respectively.

The U.S. federal and state net operating loss carryforwards begin to expire in 2019 and 2019, respectively and the U.K. NOLs can be carried forward indefinitely.

For the year ended December 31, 2018, the Company continues to recognize its deferred tax assets in the U.K. related to OI Limited. The Company also continues to recognize the deferred tax asset for future share based deductions related to OI Global. The Company has determined that it is more likely than not that this asset of $1.1 million will be realized in the future. The Company continues to record a full valuation allowance against all other net deferred tax assets since it is not ‘more likely than not’ that these amounts will be realized.

The following table reflects the rollforward of the Company’s valuation allowance:

(in thousands)	**2018**	**2017**	**2016**
Beginning of year (January 1)	$48,098	$46,473	$43,076
(Decrease) increase in valuation allowance	(30,107)	1,625	3,397
End of year (December 31)	$17,991	$48,098	$46,473

Interest and penalties related to uncertain tax positions are recorded in tax expense and totaled $37,000, $0 and $0 for the years ended December 31, 2018, 2017 and 2016, respectively. The liability recorded for potential penalties and interest was $37,000 and $0 as of December 31, 2018 and 2017, respectively. The Company had a total recorded liability of $409,000 and $0 related to uncertain tax positions, inclusive of penalties and interest, as of December 31, 2018 and 2017, respectively, which is included in accrued liabilities in the consolidated balance sheets.

The Company did not have any gross uncertain tax positions prior to December 31, 2017.

The aggregate changes in the balance of gross uncertain tax positions, which excludes interest and penalties, for the year ended December 31, 2018 were as follows (in thousands):

Balance at December 31, 2017	$—
Settlement/decreases related to tax positions taken during prior years	—
Increases related to tax positions taken during prior years	372
Increases related to tax positions taken during the current year	—
Balance at December 31, 2018	$372

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The Company generates research and development credits in the United Kingdom which are refundable if a current year loss is incurred. In the United Kingdom for the year ended December 31, 2018, no amounts were reimbursed for research and development tax credits.

The SEC staff issued SAB 118 which allowed the Company to record provisional amounts for the impact of the TCJA during a measurement period which is similar to the measurement period used when accounting for business combinations. At December 31, 2017, the Company made a reasonable estimate of the effects of the TCJA on our existing deferred tax balances. As of December 31, 2018 the Company has completed its review of the TCJA and noted no material changes to our initial assessment.

14. Intellectual property—license agreements

The Company entered into three license agreements by which it has secured certain patent rights that are necessary to make, use and sell the T-SPOT.*TB* test. In November 2013, one of these license agreements, with Oxford Innovation, was terminated in connection with the assignment by Oxford Innovation to the Company of certain intellectual property rights. The Company has ongoing obligations to make certain payments to Oxford Innovation while the assigned patents remain in force in certain countries.

On June 30, 2017, we entered into a Release and Settlement Agreement, or the Settlement Agreement, with Statens Serum Institut, or SSI, to resolve outstanding disputes arising from the license agreement with SSI. The terms of the Settlement Agreement are confidential. Based on the Settlement Agreement, we no longer expect to pay royalties to SSI.

The Company’s existing license agreements related to its T-SPOT.*TB* test, as well as its previous license from Oxford Innovation, are generally exclusive in the stated field, cover a worldwide territory, are royalty-bearing and give the Company the right to grant sublicenses. The Company has minimum royalty obligations under each existing license agreement, which continue so long as patents licensed under the agreement remain unexpired. The minimum contractual royalty payments, including ongoing minimum payment obligations to Oxford Innovation after December 31, 2018 are set forth in the license agreements and supplier purchase obligations table in Note 16. *Commitments and contingencies*, to these consolidated financial statements.

The Company incurs royalties under each existing license agreement, has incurred royalties under the Oxford Innovation license agreement, and will incur continuing payment obligations to Oxford Innovation that are treated as royalties in these financial statements, based on its product and service revenue. The aggregate royalty expense relating to the three license agreements amounted to $1.1 million, $2.8 million and $5.2 million for the years ended

December 31, 2018, 2017 and 2016, respectively. The Company paid other license-related expenses, including patent prosecution expenses, milestone payments and assignment fees due to these licensors, amounting to $83,000, $80,000 and $161,000 for the years ended December 31, 2018, 2017 and 2016, respectively. The aggregate royalty rate paid by the Company in the years ended December 31, 2018, 2017 and 2016, as a percentage of the gross product and service revenue of the Company, was 2%, 5% and 11%, respectively.

15. Employee benefit plans

In the United States, the Company has adopted a defined contribution plan (the U.S. Plan) which qualifies under Section 401(k) of the Internal Revenue Code. All U.S. employees of the Company who have attained 21 years of age are eligible for participation in the U.S. Plan upon employment. The effective date of the U.S. Plan was January 1, 2008. Under the U.S. Plan, participating employees may defer up to the Internal Revenue Service annual contribution limit. The Company began matching employee contributions as of July 1, 2016 and paid $314,000, $277,000 and $126,000 in matching contributions in the years ended December 31, 2018, 2017 and 2016, respectively.

In the United Kingdom, the Company has adopted a defined contribution plan (the U.K. Plan) which qualifies under the rules established by HM Revenue & Customs. The U.K. Plan allows all U.K. employees to contribute a minimum of 5% of salary with no maximum limit. The contribution is matched by the Company, up to a maximum of 5% of salary. The Company paid to the U.K. Plan $685,000 in contributions in the year ended December 31, 2018, $613,000 in the year ended December 31, 2017 and $636,000 in the year ended December 31, 2016.

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16. Commitments and contingencies

Operating leases

At December 31, 2018, the Company leases facilities under seven non-cancelable operating leases, with terms that expire between 2019 and 2033. The Company leases office, storage/warehouse, laboratory and manufacturing space in Abingdon, U.K., which leases are due to expire at various dates from June 11, 2019 to June 18, 2033. On March 1, 2013, the Company signed a five year lease for its U.S. corporate headquarters in Marlborough, Massachusetts. In August 2015, the Company entered into a lease amendment for this location to extend the term of the lease by two years through October 31, 2020. In addition, the lease amendment expanded the Company's office space at this location by 7,600 square feet to a new total of 22,100 square feet. The base rent for the combined space over the lease term will range from an initial low of $36,000 per month, which includes $12,000 per month for the expansion space commencing in early 2016, to a high of $39,000 per month. The Company will have an option to extend the lease for one additional term of five years.

In connection with the sale of our U.S. Laboratory Services Business to Quest, we entered into a sublease with Quest for approximately 9,000 square feet of warehousing and office space in Norwood, Massachusetts. The sublease expires in November 2020. The base rent for the space subject to sublease is approximately $17,000 per month.

In June 2018, the Company entered into a lease for new space in Abingdon, England, which extends through June 2033 that will allow it to combine its manufacturing, laboratory, storage and office operations into a single facility. The base rent on the facility over the lease term will range from $39,000 per month to $79,000 per month. Select functional groups began moving into the facility during the third quarter of 2018.

Future minimum lease payments required under the non-cancelable operating leases in effect as of December 31, 2018 are as follows:

(in thousands)	**December 31, 2018**
2019	$ 2,024
2020	1,848
2021	972
2022	855
2023	855

Thereafter	7,558
Total minimum lease payments	$ 14,112

Rent expense is calculated on a straight-line basis over the term of the lease. Rent expense recognized under operating leases totaled $2.3 million, $1.6 million and $1.1 million for the years ended December 31, 2018, 2017 and 2016, respectively.

Purchase commitments

The Company has license agreements with third parties that provide for minimum royalty, license, and exclusivity payments to be paid by the Company for access to certain technologies. In addition, the Company pays royalties as a percent of revenue as described in Note 14. *Intellectual property—license agreements*, to these consolidated financial statements. In addition, the Company has outstanding purchase obligations to its suppliers.

Future minimum payments required under license agreements and supplier purchase obligations in effect as of December 31, 2018 are as follows:

(in thousands)	**License agreements**	**Supplier purchase obligations**	**Total**
2019	$ 262	$ 8,723	$8,985
2020	134	—	134
2021	59	—	59
2022	59	—	59
2023	59	—	59
Thereafter	695	—	695
Total minimum payments	$ 1,268	$ 8,723	$9,991

Legal contingencies

The Company is subject to claims and assessments from time to time in the ordinary course of business. The Company does not believe that any such matters, individually or in the aggregate, will have a material adverse effect on the Company’s business, financial condition, results of operations or cash flows.

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Indemnification

In the normal course of business, the Company enters into contracts and agreements that contain a variety of representations and warranties and provide for general indemnification. The Company's exposure under these agreements is unknown because it involves claims that may be made against the Company in the future, but that have not yet been made. To date, the Company has not paid any claims or been required to defend any action related to its indemnification obligations. However, the Company may record charges in the future as a result of these indemnification obligations.

In accordance with its articles of association, the Company has indemnification obligations to its officers and directors for certain events or occurrences, subject to certain limits, while they are serving at the Company's request in such capacity. There have been no claims to date, and the Company has director and officer insurance that may enable it to recover a portion of any amounts paid for future potential claims.

17. Geographic revenue and long-lived assets distribution

The Company is domiciled in the United Kingdom and operates in three geographies: the United States, Europe and the Rest of the World (ROW), and Asia. Following is geographical information regarding the Company's revenues for the years ended December 31, 2018, 2017 and 2016 and the Company's long-lived assets as of December 31, 2018 and 2017.

	Revenue			**Long-lived assets**	
	Years ended December 31,			**As of December 31,**	
(in thousands)	**2018**	**2017**	**2016**	**2018**	**2017**
United States	$16,442	$15,720	$10,372	$1,685	$1,071
United Kingdom	3,626	3,041	2,620	5,248	1,487
Europe and ROW (excluding United Kingdom)	5,527	5,095	4,368	101	132
Europe and ROW	9,153	8,136	6,988	5,349	1,619
Asia	34,158	30,877	29,628	110	74
Total	$59,753	$54,733	$46,988	$7,144	$2,764

China represented approximately 48%, 46% and 44% of Asia revenue in 2018, 2017 and 2016, respectively. Japan represented approximately 50%, 51% and 55% of Asia revenue in 2018, 2017 and 2016, respectively.

18. Acquisition activity

Imugen, Inc.

On July 1, 2016, the Company acquired substantially all of the assets of Imugen, a privately owned Massachusetts corporation focused on the development and performance of testing for tick-borne diseases. The assets acquired primarily related to Imugen's proprietary testing technology and its Clinical Laboratory Improvements Amendment, or CLIA, approved and College of American Pathologists, or CAP, approved laboratory in Norwood, Massachusetts.

The consideration for the acquisition of Imugen consisted of $22.2 million in cash. The Company filed the required financial statements (including pro forma financial statements) relating to the acquisition on a Form 8-K/A on September 9, 2016.

The acquisition of Imugen was accounted for under the acquisition method of accounting and the purchase price allocation was provisionally prepared during the third quarter of 2016. These provisional amounts were finalized during the fourth quarter of 2016.

The table below summarizes the purchase price of the Imugen acquisition and the fair value of identified assets acquired at the acquisition date (in thousands):

Assets acquired:	
Property and equipment	$655
In-process research and development	9,200
Technology - clinical	5,100
Customer relationships	2,700
Trademarks / trade names	1,900
Total assets acquired	19,555
Add: Goodwill	2,645
Total consideration transferred	$22,200

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On the date of the acquisition, the fair value of acquired intangible assets was determined to be $18.9 million using primarily the excess earnings method with significant inputs that are not observable, including estimates of the timing and cost required for product approval, revenue growth, gross margin, operating expenses and a discount rate of approximately 22%. These intangible assets were considered to be Level 3 fair value assets due to the significant estimates and assumptions used by management in establishing the estimated fair value.

Goodwill of approximately $2.6 million represented the excess of the purchase price of the acquired business over the fair value of the underlying net tangible and identifiable intangible assets and represented the expected synergistic benefits of the transaction, which related to an increase in future revenues for the Company as a result of leveraging Imugen's systems and expertise of its employees. The goodwill also related to the knowledge and experience of the workforce in place. Goodwill and IPR&D are indefinite-lived intangible assets and are not amortized. Rather, they are reviewed for impairment at least annually. Goodwill related to the Imugen acquisition is deductible for tax purposes over a period of 15 years.

During the year ended December 31, 2016, the Company incurred transaction costs of $475,000 associated with the acquisition of Imugen that were recorded within general and administrative expense in the statement of operations.

Actual results of operations for the year ended December 31, 2016 acquired from Imugen are included in the consolidated financial statements from the date of the acquisition, including revenues in the amount of $7.0 million and income from operations of $730,000, not including transaction costs.

See Note 7. *Goodwill and intangible assets* for information regarding impairment charges recorded on the intangible assets recorded in the acquisition of Imugen.

With the exception of the blood donor screening business, the bulk of the remaining assets acquired from Imugen were sold to Quest in the Transaction.

Immunetics, Inc.

On October 12, 2016, the Company, through its indirect subsidiary, Oxford Immunotec, Inc., acquired Immunetics, a Massachusetts based diagnostics company focused on developing specialized tests for infectious diseases, including tick-borne diseases, such as Lyme disease. The assets acquired primarily related to IPR&D for a test for Babesia, fixed assets, customer relationships, the "Immunetics" trade name, Immunetics' proprietary testing technology for Lyme disease, and various government grants in progress at the time.

Total consideration consisted of $6.0 million in cash and up to an additional $6.0 million in cash payable on the achievement of certain revenue thresholds and pipeline related milestones over the following three years.

The acquisition of Immunetics was accounted for under the acquisition method of accounting and the purchase price allocation was provisionally prepared during the fourth quarter of 2016. In the second quarter of 2017, the Company finalized the accounting for the acquisition and recorded the following measurement period adjustments:

- the fair value of the acquired inventory decreased by $45,000 with corresponding increases to the clinical technology asset of $22,500 and to goodwill of $22,500
- the fair value of the acquired customer relationships decreased by $50,000 with a corresponding increase to goodwill
- the fair value of the Immunetics trade name decreased by $130,000 with a corresponding increase to goodwill
- goodwill decreased by $58,000 due to changes in deferred taxes

The impact on the consolidated statement of operations for the year ended December 31, 2016 was a $44,000 reduction in cost of product revenue, a $26,000 reduction in sales and marketing expense and a $58,000 increase in income tax expense.

The Company paid approximately $655,000 in transaction costs associated with this transaction, which was included in general and administrative expense in the statement of operations for the year ended December 31, 2016.

Total consideration was (in thousands):

Cash consideration	$6,000
Estimated fair value of contingent consideration	3,444
Total consideration transferred	$9,444

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The table below summarizes the final purchase price allocation for the Immunetics acquisition (in thousands):

Assets acquired:	
Cash	$285
Accounts receivable, net	347
Inventory, net	375
Prepaid expenses and other assets	199
Property and equipment	787
In-process research and development	6,970
Customer relationships	350
Trade name	160
Technology – clinical	883
Grants	50
Total assets acquired	10,406
Liabilities assumed:	
Accounts payable	(319)
Accrued liabilities	(739)
Other liabilities	(1,226)
Total liabilities assumed	(2,284)
Net assets acquired	8,122
Add: Goodwill	1,322
Total consideration transferred	$9,444

On the date of the acquisition, the fair value of acquired intangible assets was determined to be $8.4 million using primarily the excess earnings method with significant inputs that are not observable, including estimates of the timing and cost required for product approval, revenue growth, gross margin, operating expenses and discount rate rates ranging between 21.6% and 60.2%, depending on the levels of risk inherent in the various intangible assets. We considered these intangible assets to be Level 3 fair value assets due to the significant estimates and assumptions used by management in establishing the estimated fair value.

Actual results of operations for the year ended December 31, 2016 acquired from Immunetics were included in the consolidated financial statements from the date of the acquisition, including revenues in the amount of $392,000 and loss from operations of $813,000, not including transaction costs.

Goodwill of approximately $1.3 million represented the excess of the purchase price of the acquired business over the fair value of the underlying net tangible and identifiable intangible assets and represented the expected benefits of the transaction, which related to an increase in future revenues for the Company as a result of leveraging Immunetics' systems and expertise of its employees. The goodwill was also related to the knowledge and experience of the workforce in place. Goodwill is an indefinite-lived intangible asset and is not amortized. Rather, it is reviewed for impairment at least annually. There was no evidence of any goodwill impairment at December 31, 2018 and there were no goodwill impairment charges during the year ended December 31, 2018. The goodwill recognized was not

deductible for tax purposes.

See Note 7. *Goodwill and intangible assets* for information regarding impairment charges recorded on the intangible assets recorded in the acquisition of Immunetics.

The remaining definite-lived intangible assets recorded in the acquisition of Immunetics were written-off in the fourth quarter of 2018, as a result of the Company's change in strategic focus following the Transaction with Quest.

19. Discontinued operations

As previously disclosed, on September 25, 2018, Oxford Immunotec Global PLC (the "Company"), entered into a Limited Liability Company Interest Purchase Agreement (the "Purchase Agreement") with Quest Diagnostics Incorporated, a Delaware corporation ("Quest"), Oxford Immunotec Limited, a limited company incorporated in England and Wales and a wholly owned subsidiary of the Company ("Oxford Limited") and Oxford Immunotec, LLC, a Delaware limited liability company (formerly known as Oxford Immunotec, Inc., a Delaware corporation) and a wholly owned subsidiary of the Company ("Oxford LLC"), pursuant to which Oxford Limited agreed to sell, and Quest agreed to acquire, the Company's U.S. laboratory services business (the "U.S. Laboratory Services Business") for gross proceeds of $170 million in cash (the "Transaction"). Of this amount, approximately $32.3 million was paid directly to MidCap in settlement of all amounts due, which included prepayment and exit fees of approximately $2.3 million as described in Note 9. *Loans payable*.

As contemplated in the Purchase Agreement, Oxford Immunotec USA, Inc., a Delaware corporation and a newly formed wholly owned subsidiary of Oxford Limited ("Oxford USA"), joined the Purchase Agreement by way of a Joinder Agreement dated October 1, 2018.

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The Transaction was consummated in accordance with the terms and conditions of the Purchase Agreement on November 6, 2018, or the Closing Date. Prior to and in connection with consummation of the Transaction, Oxford USA and Oxford LLC carried out a corporate restructuring pursuant to which (i) the assets and businesses of Oxford LLC other than the U.S. Laboratory Services Business were transferred to Oxford USA and (ii) Oxford LLC was converted into a limited liability company.

The U.S. Laboratory Services Business at the time of the sale had a carrying value of $27.9 million. We recorded a gain of $146.0 million, which amount is included in income (loss) from discontinued operations before income taxes in our consolidated statement of operations for the year ended December 31, 2018.

Additionally, pursuant to the terms of the Purchase Agreement, the parties entered into certain ancillary agreements as of the Closing Date, including: (i) a transitional services agreement, or TSA, that will continue, unless otherwise terminated, until each service included in the TSA has been completed, (ii) a technology license agreement that will remain in effect until the date of expiration or lapse of the last to expire or lapse Blood Stability Patent and (iii) a long-term supply agreement, or the Supply Agreement, pursuant to which Oxford USA agreed to sell, and Quest agreed to purchase, T-SPOT.*TB* test kits and related accessories from Oxford USA. The Supply Agreement will last for a period of seven years after the effective date, unless a party to the Supply Agreement terminates it early, as provided for in the Supply Agreement. In addition, the parties entered into a strategic collaboration agreement to drive continued growth of T.SPOT.TB testing in the U.S. that will remain in effect until the expiration or termination of the Supply Agreement.

In conjunction with the Purchase Agreement, Quest has agreed to purchase kits and accessories from the Company for an initial period of seven years after the effective date of the Purchase Agreement unless a party to the Purchase Agreement earlier terminates, as provided for in the Purchase Agreement.

During the year ended December 31, 2018 and 2017, Oxford Immunotec Limited sold kits to its discontinued operations, Oxford Immunotec, Inc. for use in the lab services business of $8.0 million and $8.4 million, respectively, that were eliminated in the Company’s consolidated results.

Transaction expenses of $3.3 million, primarily comprised of investment banking, legal, and accounting fees related to the pending disposition, were included in general and administrative expense for the year ended December 31, 2018.

The table below provides a reconciliation of the carrying amounts of major classes of assets and liabilities of the discontinued operations that are disclosed in these notes to the consolidated financial statements to the total assets and liabilities of the disposal group classified as assets and liabilities of discontinued operations that are presented separately in the consolidated balance sheets. The assets and liabilities of the disposal group presented as assets and

liabilities of discontinued operations have been reclassified in the Company's consolidated balance sheet as of December 31, 2017.

(in thousands)	**December 31, 2017**
Carrying amounts of major classes of assets included as part of discontinued operations:	
Accounts receivable, net	$ 10,961
Inventory, net	3,005
Prepaid expenses and other assets	315
Total major classes of current assets of the discontinued operations	14,281
Property and equipment, net	6,303
Goodwill	1,484
Other intangible assets, net	6,813
Other assets	185
Total major classes of noncurrent assets of the discontinued operations	14,785
Total assets of the disposal group classified as assets of discontinued operations in the consolidated balance sheets	$ 29,066
Carrying amounts of major classes of liabilities included as part of discontinued operations:	
Current liabilities:	
Accounts payable	$ 1,290
Accrued liabilities	3,326
Other liabilities	14
Total major classes of current liabilities of the discontinued operations	4,630
Total major classes of noncurrent liabilities of the discontinued operations	48
Total liabilities of the disposal group classified as liabilities of discontinued operations in the consolidated balance sheets	$ 4,678

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The following table presents the results of discontinued operations:

	Year Ended December 31,		
(in thousands)	2018	2017	2016
Major classes of line items constituting income (loss) from discontinued operations before income taxes:			
Service revenue	$53,325	$56,700	$45,705
Cost of service revenue	34,662	36,613	29,596
Gross profit	18,663	20,087	16,109
Research and development	5,751	5,866	4,542
Sales and marketing	7,592	8,963	8,106
General and administrative	3,593	4,917	4,232
Income (loss) from discontinued operations before income taxes	1,727	341	(771)
Gain on disposition	145,982	—	—
Income tax expense	(39,435)	—	—
Income (loss) from discontinued operations	$108,274	$341	$(771)

20. Restructuring

During the third quarter of 2017, the Company's management committed to a plan to terminate various government grants that were acquired as part of the acquisition of Immunetics. As a result, the Company terminated 15 employees during the fourth quarter of 2017 and recorded restructuring charges of $169,000 in research and development expense and $13,000 in general and administrative expense.

A summary of these charges and payments made to date are included in the below table. Accrued restructuring costs at December 31, 2018 and 2017 are included in accrued liabilities in the accompanying balance sheet.

(in thousands)	**Severance**
Balance at December 31, 2016	$ —
Charge for restructuring	182
Payments during 2017	(108)
Balance at December 31, 2017	74
Payments during 2018	(70)
Balance at December 31, 2018	$ 4

In addition to the items listed above, the Company recorded charges in the third quarter of 2017 of $28,000 to write-off equipment having no future benefit to the Company and $26,000 to write-off the unamortized balance of the

grant intangible.

21. Settlement expense

On June 18, 2018, the Company entered into a Settlement Agreement with the former shareholders of Immunetics, Inc., or the Immunetics Settlement Agreement, to resolve disputes arising from the Agreement and Plan of Merger dated October 12, 2016. The terms of the Immunetics Settlement Agreement are confidential. The Company has no further obligations under the Immunetics Settlement Agreement.

On June 30, 2017, the Company and Statens Serum Institut, or SSI, entered into a Release and Settlement Agreement, or the SSI Settlement Agreement, to resolve outstanding disputes arising from the license agreement with SSI. The terms of the SSI Settlement Agreement are confidential.

22. Litigation settlement income

In December 2017, as part the settlement of the Company's patent infringement action, the Company received a one-time, lump sum payment of $27.5 million from Qiagen. The income from the settlement was recorded as a separate item in the other income (expense) section of the Company's consolidated statement of operations. See "Legal Proceedings" for more information.

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23. Subsequent events

Effective March 5, 2019, the Remuneration Committee of the Board of Directors approved the grant of equity awards to certain employees of the Company, to be issued in the form of share options and restricted share units from the Oxford Immunotec Global PLC 2013 Share Incentive Plan. The number of share options and restricted share units to be granted will be determined based on the closing price of the Company’s ordinary shares on the date of grant.