

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, 2016
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 and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post 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 or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act (check one):

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

(Do not check if a smaller reporting company)

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 February 21, 2017, there were 22,712,311 Ordinary Shares, nominal value £0.006705, of Oxford Immunotec Global PLC outstanding.

As of June 30, 2016, 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 \$196,841,358.

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, 2016.

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,” “predict,” “project,” “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 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 service our debt and meet the obligations thereunder;
- our ability to further develop, commercialize and achieve market acceptance of our current and future products;
- our ability to obtain regulatory body clearance to market any of our products;
- our ability to successfully develop and complete the acquired in process research and development, or IPR&D, program and profitably commercialize the underlying product candidates before our competitors develop and commercialize similar products, or at all;
- continued demand for diagnostic products for tuberculosis and the development of new market opportunities;
- our ability to compete successfully and to maintain and expand our sales network;
- decisions by insurers and other third-party payors with respect to coverage and reimbursement;
- 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, 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 reform, on our business;
- potential changes to the Patient Protection and Affordable Care Act of 2010, or PPACA;
- the impact of product liability, intellectual property and commercial litigation on our business;
- our ability to comply with 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;
- our ability to protect and enforce our intellectual property rights;
- our status as an emerging growth company and as an English company listing ordinary shares in the U.S.;

- the volatility of the price of our shares, substantial future sales of our 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.
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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 under-served immune-regulated conditions. Our current product lines and development activities principally focus on four areas: infectious diseases, transplantation, autoimmune and inflammatory disease and immune-oncology. We believe these areas are particularly 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. These immune-regulated conditions also tend to be characterized by wide variation in presentation and progression and often require expensive therapies, making diagnostic tests that can better categorize patients and inform treatment pathways particularly useful and cost-effective. Lastly, we believe these conditions to be under-served as the industry lacks the appropriate techniques to prosecute the immune responses which are driving these conditions.

On July 1, 2016, we acquired substantially all of the assets of Imugen, Inc., or Imugen, a privately owned Massachusetts corporation specializing in developing and commercializing proprietary tests for tick-borne diseases, including Lyme disease.

On October 12, 2016, we acquired Immunetics, Inc., or Immunetics, a privately owned Massachusetts corporation focused on developing specialized tests for infectious diseases, including tick-borne diseases, such as Lyme disease. Total consideration consisted of \$6 million in cash and up to an additional \$6 million in cash payable on the achievement of certain revenue thresholds and pipeline related milestones over the next three years.

Our first product, the T-SPOT[®].TB test, is used to test for tuberculosis, or TB, infection and leverages our proprietary 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. Interferon-gamma release assays, or IGRAs, such as our T-SPOT.TB test have been included in clinical guidelines for TB testing in at least 34 countries, including the United States, several European countries and Japan. In addition, we have established reimbursement for our test in the United States, as well as a Current Procedural Terminology, or CPT², code that is unique to our test. Outside the United States, we have established reimbursement in several countries where reimbursement applies, including Japan, Switzerland and Germany. We have also established the cost-effectiveness of our test in several published studies.

Our second product line is a range of assays for tick-borne diseases, such as Lyme disease, obtained through the acquisitions of Imugen and Immunetics in 2016. Tick-borne disease is the collective name for diseases passed to humans through the bite of an infected tick. The most prevalent and well known tick-borne disease is Lyme disease, but there are others such as anaplasmosis, ehrlichiosis, and babesiosis. If left unrecognized, and therefore untreated, they may go on to cause significant downstream morbidity, including in rare cases death. Our diagnostic tests for tick-borne infections include multiple proprietary laboratory developed tests, or LDTs, offered from our Clinical and Laboratory Improvement Amendments, or CLIA, certified and College of American Pathologists, or CAP, accredited laboratory in Massachusetts and an FDA cleared test kit utilizing the C6 peptide, which is a marker specific to Lyme disease. Our C6 Lyme ELISA[™] kit is also CE marked in the European Union. Our tick-borne disease tests utilize molecular methods (such as polymerase chain reaction) and techniques to prosecute the immune system, and offer advantages over current tests and are widely reimbursed in the U.S. using existing codes on fee schedules.

Our third product line is a series of assays for use in blood screening, building upon our expertise in tick-borne disease. The parasite *Babesia microti* which causes babesiosis can be transmitted through the transfusion of infected blood, as well as by the bite of an infected tick. We are developing three assays for use in screening the U.S. blood supply for *Babesia microti*. We have submitted biological license applications, or BLAs, for these three assays and they are currently under review by the FDA.

Our T-SPOT.CMV and T-SPOT.PRT tests are part of our fourth product line focused on the transplantation market. Both tests utilize our T-SPOT technology platform and are laboratory developed tests, or LDTs, performed in our CLIA certified, CAP accredited laboratory in Tennessee. Both the T-SPOT.CMV and T-SPOT.PRT tests are CE marked in the European Union. The T-SPOT.CMV test measures the strength of a patient's cellular immune response to CMV specific antigens and provides information that may be useful in informing management strategies of patients at risk of CMV infection and disease, such as transplant patients. The T-SPOT.PRT test assesses a solid organ transplant candidate's T cell response to foreign tissue, or alloreactivity, and may help clinicians identify patients at increased risk of T cell mediated rejection post-transplant. We continue to take a measured approach to market introduction of these tests as we await final results of our two pivotal clinical studies involving these tests.

¹“T-SPOT[®],” “T-Cell Xtend[®],” “Oxford Diagnostic Laboratories[®],” “ODL[®],” “SpiroFind[®],” “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.

² CPT is a registered trademark of the American Medical Association.

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In addition to our existing product lines, we continue to pursue development programs targeting other immune-regulated conditions, as well as applications of our T-SPOT technology platform in immune-oncology. Product development activities are inherently uncertain, and there can be no assurance that we will be able to obtain regulatory body clearance to market any of our products, or if we obtain clearances that we will successfully commercialize any 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.

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. We believe the U.S. market opportunity for our tests directed to Lyme and other tick-borne diseases exceeds \$450 million and the U.S. market opportunity for our products directed to transplantation to be in excess of \$450 million, although our market sizing estimates remain preliminary. We have not yet sized the market opportunity for our blood screening assays, as the volume of sales or pricing remain unknown, nor have we sized the market for the application of our technology in immune-oncology given the early stage of this program.

We are a global business with 432 employees, including sales and marketing teams on three continents, and laboratories in the United States and the United Kingdom. In 2016, we derived approximately 42% of our revenue from outside the United States and our current customer base includes more than 3,000 active customers, such as hospitals, public health departments, physician offices, commercial testing laboratories, importers and distributors.

Our focus

Our products and research and development activities focus on proprietary tests for the management of under-served immune-regulated conditions. Large populations of patients have immune-regulated conditions that are often chronic conditions requiring active management through monitoring. Testing that allows better categorization of patients and yields insights into the most likely successful treatment path facilitates personalized medicine, directing therapies to patients in whom they are more likely to work and saving healthcare dollars. We view this space as being underserved by traditional diagnostic companies which lack appropriate techniques to prosecute the immune system.

Immune-regulated conditions encompass a broad spectrum. We are focused on four principal areas: infectious diseases, transplantation, autoimmune and inflammatory disease and immune-oncology.

Understanding immune-regulated conditions requires interrogation of the immune system. The human immune system is composed of three principal branches: innate immunity, cellular (T cell) immunity and humoral (B cell and antibody-based) immunity. Through our proprietary T-SPOT technology platform we can efficiently measure marker-specific T cell and innate immune responses at a single cell level and thereby inform the diagnosis, prognosis and monitoring of patients with immune-regulated conditions. We employ a proprietary quantitative method to detect antigen-specific cells releasing immune messenger molecules, called cytokines, released by effector T cells or innate immune 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.

Our T-SPOT technology offers many technical advantages that make it well suited to support our focus on immune-regulated conditions including high analytical sensitivity, 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 treatment for cancer.

We employ other proprietary testing methods in our assays directed to tick-borne diseases that support our differentiated test offerings. Our test methods provide increased insight into antibody responses to tick-borne pathogens, which may help clinicians understand the disease state more completely. Our test kit for Lyme disease employs a patented synthetic peptide derived from a protein that is highly specific for Lyme disease. We also 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- γ antibodies, and our quality control testing procedures. Further, we have developed proprietary methods designed to achieve rapid throughput in assay performance across all of our product lines. These methods involve specific protocols throughout the assay process and have been developed in our service and research and development laboratories.

Our Products

Tuberculosis

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 smokers, 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 WHO, approximately one-third of the world's population, over two billion people, is 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 2015 approximately 10 million people were diagnosed with active TB disease, of which approximately 1.8 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 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 and screening of certain U.S. military personnel for LTBI is included in military guidelines. 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 mandated by many states to include additional populations, such as day care staff, school teachers and pupils, and police officer candidates.

In total, we estimate that there are 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 to be 28 million each year, for a combined market size of 50 million LTBI tests annually.

The primary test currently used for TB screening is the 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.

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 *M. tuberculosis*, 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 *M. tuberculosis*. 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.

We currently offer our T-SPOT.*TB* test in either an *in vitro* diagnostic kit or a service format. In the former, we sell test kits and associated accessories to laboratories for them to perform the testing themselves. In the latter, we have established clinical testing laboratories in the United States and the United Kingdom, where we perform our T-SPOT.*TB* test on samples sent to us by customers. In these markets, we have found that many customers prefer to send samples to us rather than perform their own analysis on-site. We market our service offering under the name Oxford Diagnostic Laboratories®, or ODL®.

Our test is widely reimbursed both internationally, with reimbursement established in China, Japan and Germany, and in the U.S., where we have established a unique CPT code for our test. Based upon the combination of public and private payors, we now have over 300 million covered lives in the U.S.

Although primarily designed for use in detecting LTBI, our test can also be used to assist in the diagnosis of active TB disease, particularly in suspected cases where conventional diagnostic methods such as chest x-ray or sputum smear are inconclusive. Because infection is a pre-requisite for disease, ruling out TB infection can aid physicians in diagnosing a different disease or condition. Our test has been included in guidelines in several countries for this purpose, such as those from the Netherlands, France, Ireland and Italy.

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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 at least 34 countries, including the United States, several European countries and Japan.

In recent years, the use of IGRAs has been increasingly recommended. For example, 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.

We believe that these guidelines, and similar national guidelines outside the United States, 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 medical, logistical 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 answering customer questions. These teams are supported by marketing activities, which include advertising, medical education, attendance at scientific meetings and other awareness-raising activities.

In 2016, we derived more than 91% of our revenue from sales of our T-SPOT.*TB* test.

Tick-borne diseases

Tick-borne diseases is the collective name for diseases passed to humans through the bite of an infected tick. Tick-borne diseases are increasing in incidence. In the United States, it is estimated that over 300,000 people are diagnosed each year with Lyme disease, the most common tick-borne disease.

Coinfection may occur when the tick carries more than one pathogen. Studies have suggested that, depending on geographical location, up to 45% of patients infected with *Borrelia burgdorferi*, the causative organism of Lyme disease, may also be infected with other organisms that cause tick-borne diseases, such as *Babesia microti*. Discerning the correct diagnosis can be challenging. The CDC recommended approach for serological diagnosis of Lyme disease involves a 2-tier testing methodology that relies on detection of antibodies. While these guidelines are effective in many situations, serological tests have detection limitations during the first few weeks of infection and the guidelines do not require testing for co-infection.

Further, the challenges of diagnosing Lyme disease differ based on when patients present with symptoms. Diagnosis of early Lyme disease requires high sensitivity to detect infection. Late Lyme disease requires more specific and cost-effective testing to replace or streamline 2-tier testing and to indicate therapy response and/or cure.

Our portfolio of tick-borne disease tests use a variety of analytical methods to meet the needs of clinicians and laboratorians in diagnosing and treating patients with tick-borne infections. Our Massachusetts laboratory uses antibody capture, enzyme immunoassay, or EIA, western blot, polymerase chain reaction, or PCR, and immunofluorescence assay, or IFA, methods to detect serological and molecular evidence of the particular organisms associated with tick-borne disease. We also maintain an archive of up to five years' worth of specimens with serological evidence of infection. This may provide customers with a comparative analysis of current and past samples to provide further information to clinicians about their patients and disease state.

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. The test has a one hour turnaround time and due to its improved performance over several other currently available tests, may reduce costs associated with sending out more samples for confirmatory tests.

We currently utilize our sales force to market our tick-borne disease tests directly in the U.S. Outside the U.S., we rely on both our salesforce and independent distributors to market our C6 Lyme ELISA kit.

Babesia microti Blood Screening

Babesiosis is a tick-borne disease characterized by a wide spectrum of clinical manifestations that range from asymptomatic to severe acute or even fatal illness. While the disease is generally mild to moderate in children and young healthy adults, it is more severe in neonates, the elderly and immunocompromised individuals such as those undergoing treatment for cancer. Babesiosis is predominately caused by a parasite called *Babesia microti*. While it is primarily transmitted through a tick bite, babesiosis can also be transmitted by blood transfusion. In fact, transfusion-transmitted babesiosis is responsible for the highest percentage (38%) of transfusion-related infectious fatalities reported to the FDA in transfusion recipients and *Babesia microti* is the highest ranking pathogen in the U.S. transmitted by blood transfusion for which no donor screening is available. The transmission risk of *Babesia microti* is comparable to the transmission risk of HIV, HBV, and HCV prior to the implementation of routine blood screening programs for these pathogens. Screening for *Babesia microti*, therefore, has become a priority for the FDA.

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Through our acquisition of Imugen, we have an antibody and PCR test for *Babesia microti* for use in blood screening. Our clinical trial, completed under an FDA Investigational New Drug, or IND, application and in cooperation with the American Red Cross screened approximately 90,000 blood samples to evaluate the effectiveness of our testing regime in detecting *Babesia microti*-infected donors. No reported cases of transfusion-transmitted babesiosis were associated with the 75,331 screened donations from high risk states as compared to 14 cases per 253,031 unscreened donations. Based upon the study results, we believe our antibody and PCR tests are effective for screening blood for *Babesia microti* and have submitted two BLAs to FDA to obtain licensure for the tests. The results of the clinical trial were published in the *New England Journal of Medicine* in December 2016.

Through our acquisition of Immunetics, we have a second antibody test that may be used to screen for *Babesia microti* in blood samples. We have submitted a BLA for the test and, if approved, we would offer the test as a kit for laboratories seeking to screen units of blood for *Babesia microti* in-house.

Transplantation

Over 160,000 transplants were conducted in 2014, with 29% in the United States, 48% in Europe and 23% in the rest of the world. Kidney and hematopoietic stem cell transplants comprise the majority of the market. The majority of transplants are performed in hospitals or clinics specializing in transplantation and present a fairly concentrated sales call point.

Our products currently targeting the transplant market are the T-SPOT.CMV and T-SPOT.PRT tests. These have completed technical development and we are currently conducting clinical validation.

Our T-SPOT.CMV test measures the strength of a patient's cellular immune response to CMV infection. Once infected with CMV, the virus remains in the body for life and is an opportunistic pathogen. It is present in up to 90% of the human adult population, most of whom successfully control its progression through their T cell response. For those with weakened immune systems such as transplant recipients, however, CMV presents a significant source of morbidity. Our T-SPOT.CMV test may be a useful aid in evaluating a patient's risk of CMV infection and disease.

Our T-SPOT.PRT assay measures the functional response of an organ recipient's T cells to a panel of antigens representing foreign tissue types. Present test methods directed to assessing the likelihood of graft rejection focus only on antibody mediated rejection. Graft rejection often involves the activation of T cells. Our test is directed to inform the risk a T cell mediated rejection both pre- and post-transplant, potentially allowing clinicians to reduce rejection events and adjust immunosuppression consistent with the patient's T cell response to the graft. The test is currently available only in connection with our ongoing PROTECT study.

Our T-SPOT.CMV and T-SPOT.PRT tests are CE marked in the European Union. In the U.S., our CLIA certified and CAP accredited laboratory in Tennessee performs the tests.

Regulatory approvals and clinical validation

Tuberculosis

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 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.

Tick-borne diseases and transplantation

Our C6 Lyme ELISA kit is FDA cleared and CE marked in the European Union. The test has been the subject of over 20 peer-reviewed publications.

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Our service-based tests for tick-borne diseases are offered as laboratory developed tests from our CLIA certified, CAP accredited laboratory in Massachusetts. Our tests have been the subject of more than 30 peer-reviewed publications.

Competitive landscape

Tuberculosis

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 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[®]3-TB Gold test, or QFN. As this test also measures IFN- γ release, QFN, like our own test, is sometimes referred to generically as an IGRA.

We have been competing with QFN, or prior versions of this test, since the inception of our company over 14 years ago. Based on our experience, we believe that we have several performance advantages over QFN, 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 test notes that QFN has not been extensively evaluated in individuals with impaired or altered immune function and 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 clinical sensitivity exceeding 95%. In the clinical trials for QFN reported in its U.S. package insert, that test was shown to have overall sensitivity of 89%. We believe this allows us to differentiate our test based on accuracy.

In addition to the performance advantages we believe we have over QFN, we have developed and implemented the ability to offer our test as a service in the United States and the United Kingdom. The significant advantages of offering our test as a service include marketing opportunities created through the development of direct customer relationships, more convenient and extensive (7 days a week) access to testing via our logistics infrastructure, faster and more efficient customer on-boarding as a result of the simplicity of our pre-paid shipper boxes, and greater utility for our customers due to additional services we can provide beyond a test result.

As a result of clinical and service advantages, we have been able to negotiate a higher average selling price for our service. We believe this advantage provides us a larger addressable market than is available through selling kits as done by QFN; simply put, our revenue potential from the same testing volume is higher. We believe that this will also enable us to achieve a higher absolute profit per test. However, to the extent that national and regional laboratories offer QFN as a service, we may also face competition from them in our service offering.

The benchmark reimbursement for our T-SPOT.*TB* test is higher than for QFN in the United States, with CMS reimbursement in 2016 of \$102 per test for CPT code 86481 as opposed to CMS reimbursement of \$84 per test for CPT code 86480. We believe that this higher reimbursement provides us with pricing and access advantages in certain segments of the U.S. market.

The QuantiFERON-TB Gold Plus test, or QFN Plus, is currently available in the European Union. Early publications suggest similar performance characteristics to QFN Gold. QFN Plus also requires the use of a fourth specialized antigen-coated blood collection tube, either at the time of blood draw or later, which may increase phlebotomy complexity and time required. The additional blood collection tube may increase per-test costs for performing laboratories, as it requires an additional plate well for each sample processed. Qiagen has announced that a PMA for QFN Plus has been submitted to the FDA, and we expect to see FDA approval for this product in 2017.

¹QuantiFERON[®] is a registered trademark of Qiagen N.V.

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Tick-borne diseases

Historically, the tick-borne disease testing market has been served by undifferentiated assays focused mainly on Lyme disease. The U.S. CDC guidelines, which are now over 20 years old and were formulated when the incidence Lyme and other tick-borne diseases were far lower, recommend the use of a 2-tier methodology for Lyme disease testing consisting of an initial screening by EIA or IFA followed by a confirmatory western blot for equivocal or positive EIA or IFA results. This methodology has three limitations: 1) it relies solely on indirect serological detection of infection; 2) serology testing can be insensitive within the first few weeks following infection; and 3) it does not address testing for co-infection with other organisms that cause tick-borne diseases.

The competitive landscape for diagnostics directed to tick-borne diseases is largely fragmented in the U.S. with national laboratories, regional laboratories and specialty laboratories offering various tests utilizing a range of established technologies and laboratory techniques. Large community and academic hospitals may offer tick-borne disease testing 'in-house' i.e., within their laboratories, but it is typically limited to Lyme disease testing, as no FDA-approved test kits exist for ehrlichiosis, anaplasmosis, babesiosis and several other tick-borne diseases other than Lyme. National laboratories, including Quest Diagnostics Inc. and Laboratory Corporation of America Holdings, have broad geographic reach in the U.S. and offer a range of antibody screening and PCR tests targeting Lyme and other tick-borne diseases. Regional laboratories focus on particular geographic areas within the U.S. and differ in the variety of tick-borne disease tests offered while specialty laboratories tend to have more limited test menus, especially for tick-borne diseases other than Lyme disease.

We believe that our portfolio of tick-borne disease tests offers a significant competitive advantage relative to the existing products on the market. Our C6 Lyme ELISA kit can replace one or both of the current 2-tier tests for Lyme disease because the test has higher sensitivity in the detection of antibodies in early and late stage Lyme disease and results in fewer false positives than several competing ELISA kits. Through the combination of PCR and antibody tests, we are also able to detect the organism that causes the tick-borne disease as well as the antibody response to the organism. Our approach accommodates a wider diagnostic window and addresses more tick-borne diseases than the traditional test for Lyme disease. We also offer customers tests based on specific geographic prevalence data, which allows them to tailor the tests ordered to tick-borne diseases present in their local geographies. Additionally, for individual patients, Imugen archives test results enabling current samples to be reviewed relative to previous samples to better inform the interpretation.

Our pipeline

Infectious diseases

We are actively pursuing assays in the area of tick-borne diseases. The first assay, presently referred to as SpiroFind, targets Lyme disease and may provide both an earlier diagnosis and the ability to differentiate re-infections from prior exposure. This assay would complement our existing assays offering comprehensive testing for tick-borne infections.

Our second assay targets Rocky Mountain Spotted Fever, or RMSF. RMSF is the most lethal and most frequently reported rickettsial tick-borne disease in the United States. Although RMSF cases have been reported throughout most of the contiguous United States, five states (North Carolina, Oklahoma, Arkansas, Tennessee, and Missouri) account for over 60% of RMSF cases. The early clinical presentation of RMSF is nonspecific and may resemble a variety of other infectious and non-infectious diseases.

We have additional assays in early stages of technical development which target infectious diseases endemic to the United States, Europe and other geographies. Diseases impacting public health in the U.S. and other geographies remain a key target for our product pipeline activities in infectious diseases. Assays directed to these diseases allow us to leverage our commercial infrastructure as they have complementary call points including hospitals, physician offices and public health departments.

Transplantation

Our products currently targeting the transplant market are the T-SPOT.*CMV* and T-SPOT.*PRT* tests for which we are currently conducting clinical validation through two clinical studies. The PROTECT study is a trial designed to demonstrate the clinical value of the T-SPOT.*CMV* and T-SPOT.*PRT* tests in solid organ transplantation and has fully enrolled at sites in the U.S. and Europe. The REACT study, which focuses on hematopoietic stem cell transplant patients, is designed to demonstrate the clinical value of the T-SPOT.*CMV* test and has completed enrollment at sites in the U.S., Canada and Europe. Although enrollment is complete, the studies require real-time follow-up of patients following transplant. We expect both clinical studies to report interim data in 2017.

We estimate the total addressable market for our T-SPOT.*CMV* and T-SPOT.*PRT* assays to be in the range of \$450 million.

Immune-oncology

Our work in the area of immune-oncology remains in the early stages as we explore the areas of utility of our T-SPOT technology platform in the context of cancer immunotherapy. Specifically, we are evaluating use of our technology in connection with the rapid advancement of vaccines or therapies targeting specific cancer cell surface antigens. As our research in this area progresses, we will be refining our focus with the goal of optimizing the commercialization of our T-SPOT technology platform in the immune-oncology space.

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Our total research and development expenses were \$13.9 million, \$10.4 million, and \$7.0 million for the years ended December 31, 2016, 2015 and 2014, respectively.

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 13 issued U.S. patents, 16 issued patents in other jurisdictions, two pending U.S. patent applications and two pending patent applications 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 core technology patents contain claims to methods of measuring marker-specific effector T cell responses at a single-cell level. These methods cover the measurement of intracellular pathogens by detecting, through a quantitative method using an ELISPOT technique, the *in vitro* release of cytokines by antigen-specific effector T cells. These measurements can inform the diagnosis, prognosis and monitoring of patients with immunologically controlled diseases or conditions, such as infectious diseases, cancers and autoimmune diseases. These patents run through 2017 and 2019.

The inventions claimed in our patents and patent applications 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 2028.

We have also licensed three patents on a non-exclusive basis that relate to our T-SPOT.*CMV* test and one patent that relates to our C6 Lyme ELISA kit. In connection with our acquisitions of Boulder Diagnostics, Inc., or Boulder, and Immunetics, we gained access to additional patents that we believe may assist us to develop future diagnostic tests in the infectious disease or transplant fields. We have licensed certain patents related to the detection of antibody-secreting B cells specific for HLA and to the PCR and IFA tests performed at our Massachusetts laboratory. We also acquired a patent application relating to additional TB antigens. The expected expiration dates of the licensed patents range from October 2017 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 results 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 double digits. Our royalty burden for our T-SPOT.*CMV* test under all license 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, (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, and (iv) a pre-existing grant to a third party of non-exclusive rights under some of the patents with the right to sublicense, limited to use with ESAT-6 and CFP10 antigens, and excluding use of the ELISPOT technique for diagnosis and monitoring of TB infection, disease or therapy. We do not believe this third party has granted any sublicense rights as of December 31, 2016.

The amount we pay to Oxford Innovation for our royalty obligation is equal to a royalty rate in the low single digits and we expect this rate to be reduced for certain of our sales after the expiration of certain specified patents, which we believe will be in late 2017. Our aggregate royalty obligation payments to Oxford Innovation through December 31, 2016 have been \$2.3 million. Our royalty obligations to Oxford Innovation will cease when there are no valid patent claims still in force.

We also have a license from Statens Serum Institut, or SSI, for use of certain antigens. The license was originally entered into in 2003 and then amended in 2009. Pursuant to the license, SSI granted us an exclusive, worldwide, royalty-bearing license with the right to sublicense, to certain patents to use certain antigens in a diagnostic kit for *in vitro* diagnosis of TB in humans using an ELISPOT-based detection of interferon-gamma producing T cells using any fluid sample other than whole blood in the diagnostic assay. The last of the patents upon which we rely expired in 2016. We have not granted any sublicenses under this license.

The license contains minimum royalty obligations, but the amount of royalties due on actual sales has exceeded the minimum royalties for a number of years. We pay royalties in the Euro currency at a rate in the low double digits. Our license agreement expires, unless earlier terminated, five years after the expiration of the last to expire of individual licensed patents listed as part of the agreement at the effective date in 2003. The royalty obligations on sales of products that rely upon proprietary antigens covered by the license may continue after the expiration date of licensed patents for a period of four years at a single digit royalty rate. Our aggregate payments to SSI through December 31, 2016 for milestones and royalties, including minimum royalties, have been \$17.2 million.

Finally, 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 and 2013. 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, 2016 for signing fees, annual fees, milestones and royalties, including minimum royalties, have been \$4.8 million. Our royalty rate may be reduced, depending on the outcome of an European Patent Office, or EPO, opposition appeal and could also be reduced if Rutgers grants another license to the technology covering an ELISA format. See "Risk factors—Risks related to our intellectual property." 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.

Tick-borne disease related patents

We license patents relating to our tick-borne disease products from Roche Molecular Systems, Inc., or Roche, Life Technologies Corporation, or Life Technologies, and Tulane University, or Tulane. The licenses from Roche and Life Technologies pertain to patents covering aspects of the PCR and IFA test methods, respectively, used at our Massachusetts laboratory. Both are fully paid up licenses with no ongoing royalty obligations. The patents that are the subject of the licenses expire in 2018.

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. 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.

Trademarks and other protection

The trademarks we employ in our business include T-SPOT, T-Cell *Xtend*, Oxford Diagnostic Laboratories, ODL, the Oxford Immunotec logo, our laboratory logo, the Imugen 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 Imugen 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 proprietary processes

There are several areas in which we have developed proprietary approaches to manufacturing that we believe provide a competitive advantage not only with respect to our T-SPOT.*TB* test, but also for the other tests we perform at our laboratories. 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 have also developed a proprietary approach to conducting conformance testing and validation as part of our quality control processes. 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 proprietary 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 laboratories. In our ODL facilities, we have streamlined the workflow process in our laboratories 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.

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 2019 and our current rent for the manufacturing space is \$103,000 annually, which is subject to change. Our manufacturing facility is certified to ISO 13485 and ISO 9001. Our space in Abingdon also includes 6,400 square feet of storage/warehouse space. The lease covering this space expires in 2025 and our current rent for the storage/warehouse space is \$72,000 annually, which is subject to change.

We operate three diagnostic testing laboratories, two in the United States and one in the United Kingdom, where we process samples sent to us by our customers who choose the service format of our product offering. Our U.S. laboratory facility, located in Memphis, Tennessee performs our T-SPOT.*TB* test and develops and performs our T-SPOT.*CMV* and T-SPOT.*PRT* tests. Our current lease for the Tennessee laboratory facility covers approximately 35,000 square feet of space and expires in 2021. Our current rent under this lease is \$150,000 annually and is subject to annual increases. Our second U.S. laboratory is located in Norwood, Massachusetts and performs our tick-borne disease tests. Our current lease for the Norwood laboratory facility covers approximately 22,000 square feet of space and expires in 2021. Our current rent for the Norwood laboratory is \$412,000 annually and is subject to annual increases. We also currently lease approximately 14,000 square feet in Boston, Massachusetts, which includes a clinical and research laboratory directed to the development and testing of the products acquired from Immunetics. The lease for the Boston facility expires in July 2018. Current rent under this lease is \$263,000 annually.

Our U.K. laboratory is located in Abingdon, England, where we currently lease approximately 2,100 square feet of space, which includes 1,050 square feet for the diagnostic testing laboratory. The remaining 1,050 square feet is used for research and development and quality control. The lease on this space expires in 2019 and our current rent for the total U.K. laboratory space is \$83,000 annually, which is subject to change.

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. 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.

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The purchase agreement expires, unless earlier terminated, on December 31, 2018. 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. Pursuant to this agreement, Millipore 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, 2018. Each party has the right to terminate in the event of a material uncured default by the other party.

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, 2017, 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. 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.

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. The aggregate amount of exclusivity fees due under the agreement is, absent early termination, \$1.8 million. Our product purchases exceeded the amount of the exclusivity fee in 2016. 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 January 30, 2018, 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. If we terminate the agreement for other reasons prior to January 30, 2018, we may be obligated to pay a termination fee of up to \$0.5 million to the extent that we have not previously made other payments for the signing fee, milestone payments and actual product purchases in excess of this amount. Based on our payments to date, we do not expect to incur any termination fee if we terminate the agreement.

Life Technologies Corporation. We entered into a supply and reseller agreement with Life Technologies Corporation, or Life Tech, in 2013, amended in 2014 and again in 2016, pursuant to which we purchase and resell a product that can be used in performing assays using our T-SPOT technology. We have minimum annual purchase obligations under this agreement, as well as obligations to purchase certain amounts based on our forecasts. The agreement expires, unless earlier terminated, on December 31, 2018. 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

Given the diversity of our product and service offerings, our customers include large hospital systems, public and private institutions such as universities, public health departments and physician groups. Our customer relationships also include our distributors outside of the U.S. We believe our relationships with two of the distributors of our T-SPOT.TB test are key customer relationships.

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.

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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. In November 2016, we amended the distribution agreement to provide a certain quantity of T-SPOT.*TB* test kits at no charge for use in Fosun's discount programs in 2016, subject to 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 and 2016. 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. IVDs that are used to screen donor blood are regulated as biological products, which have two different regulatory pathways.

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 regulatory pathway to receive authorization to market an IVD intended for blood screening is by a Biologics License Application, or BLA. 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.

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Biological License Application. The BLA process is similar to a PMA in that it must be supported by detailed and comprehensive scientific evidence, including clinical data to demonstrate the safety and efficacy of the biological product for its intended use in donor blood screening. Blood screening assay development follows the same general pathway followed for drugs and vaccines. Before an application is submitted, an Investigational New Drug application (IND) must be submitted and completed. The IND describes the biological product, its method of manufacture, and quality control tests for release, as well the comprehensive clinical trial protocols. We currently have three BLAs in review with FDA.

FDA Guidance on Laboratory Developed Tests. The FDA has historically exercised enforcement discretion over the regulation of Laboratory Developed Tests, or LDTs. In October 2014, the FDA issued draft guidance for the oversight of LDTs that included notification and medical device reporting. Under the draft guidance, the FDA sought to classify LDTs as high, medium or low risk tests, which would then dictate the regulatory route to be followed for each test. In November 2016, the FDA announced that it would not finalize its guidance during 2016. It is uncertain whether the guidance in its current form will be finalized or if, and when, alternate guidance may be issued by the agency.

Post-marketing regulations and controls

Under the medical device and biological products 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 and biological products. 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.

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.

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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* and T-SPOT.*PRT* tests obtained CE marks in 2015 and our C6 Lyme ELISA kit obtained a CE mark in 2011.

Laboratory certification, accreditation and licensing

As a company engaged in the diagnostic testing business, we are required to maintain certain federal and state licenses, certificates and permits.

United States. In the United States, CLIA imposes requirements relating to test processes, personnel qualifications, facilities and equipment, record keeping, quality assurance and participation in proficiency testing, which involves comparing the results of tests on specimens that have been specifically prepared for our laboratory to the known results of the specimens. The CLIA requirements also apply as a condition for participation by clinical laboratories under the Medicare program. Under the CLIA regulations, the complexity of the tests performed determines the level of regulatory control. United States Department of Health and Human Services, or HHS, classifies our T-SPOT tests and our tests directed to tick-borne diseases as high-complexity tests. As a result, we must employ more experienced and highly educated personnel, as well as additional categories of employees.

HHS, or an organization to which HHS delegates authority, verifies compliance with CLIA standards through periodic on-site inspections. Sanctions for failure to meet these certification, accreditation and licensure requirements include suspension or revocation of the certification, accreditation or license, as well as imposition of plans to correct deficiencies, injunctive actions and civil and criminal penalties. If HHS should remove or suspend our CLIA certificates, we would be forced to cease performing testing at our U.S. laboratories in Memphis, Tennessee or Norwood, Massachusetts.

Our U.S. laboratories are also accredited by CAP. The CAP Laboratory Accreditation Program is an internationally recognized program that utilizes teams of practicing laboratory professionals as inspectors, and accreditation by CAP can often be used to meet CLIA and state certification requirements. Additionally, a few states require out-of-state laboratories to obtain a license prior to performing testing on samples originating from such states and to take certain notice or approval steps in connection with the performance by such laboratories of additional tests. The failure to maintain such licenses or approvals would force us to cease performing the applicable tests on samples originating from such a state.

United Kingdom. Our laboratory located in the United Kingdom operates under accreditation by the United Kingdom Accreditation Service, or UKAS, for the International Standard: ISO 17025:2005 (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. Because we are a healthcare provider and we conduct certain healthcare transactions electronically, we are currently a Covered Entity, and we must have in place the administrative, physical, and technical safeguards required by HIPAA, the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations. Additionally, some state laws impose privacy protections more stringent than HIPAA. 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 other applicable privacy laws. For example, there are also international privacy laws that impose restrictions on the access, use, and disclosure of health information. 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 billing and fraud and abuse laws

Although only about 15% of our U.S. diagnostics business currently involves payment by third-party payors, including government payors, we are subject to numerous laws governing billing for health care services.

Antifraud laws / overpayments. As participants in federal and state healthcare programs, we are subject to numerous federal and state anti-fraud and abuse laws. Prohibitions under some of these laws include:

- the submission of false claims or false information to government programs;
- deceptive or fraudulent conduct;
- excessive or unnecessary services or services at excessive prices; and
- defrauding private sector health insurers.

We could be subject to substantial penalties for violations of these laws, including denial of payment, obligation to issue refunds, suspension of payments from Medicare, Medicaid or other federal healthcare programs and exclusion from participation in the federal healthcare programs, as well as civil and criminal penalties and imprisonment. One of these statutes, the False Claims Act, is a key enforcement tool used by the government to combat healthcare fraud.

Numerous federal and state agencies enforce anti-fraud and abuse laws. In addition, private insurers may bring private actions. In some circumstances, private whistleblowers are authorized to bring fraud suits on behalf of the government against providers and are entitled to receive a portion of any final recovery.

U.S. federal and state “anti-kickback” and “self-referral” restrictions

Anti-kickback statute. 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.

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.

Self-referral law. We are subject to a federal “self-referral” law, commonly referred to as the “Stark” law, which provides, unless a specific exception applies, that physicians who, personally or through a family member, have ownership interests in or compensation arrangements with a laboratory are prohibited from making a referral to that laboratory for laboratory tests reimbursable by Medicare, and also prohibits laboratories from submitting a claim for Medicare payments for laboratory tests referred by physicians who, personally or through a family member, have ownership interests in or compensation arrangements with the testing laboratory.

We are subject to comparable state laws, some of which apply to all payors regardless of source of payment, and do not contain identical exceptions to the Stark law. The self-referral laws may cause some physicians who would otherwise use our laboratory to use other laboratories for their testing. Providers are subject to sanctions for claims submitted for each service that is furnished based on a referral prohibited under the federal self-referral laws. These sanctions include denial of payment, obligation to issue refunds, civil monetary payments and exclusion from participation in federal healthcare programs and civil monetary penalties. They may also include penalties for applicable violations of the False Claims Act, which may require payment of up to three times the actual damages sustained by the government, plus civil penalties of up to \$10,781 to \$21,563 for each separate false claim.

U.S. health care reform

In March 2010, the PPACA was enacted, which includes measures that have or will significantly change the way healthcare is financed by both governmental and private insurers. However, potential changes to the PPACA may result from the 2016 U.S. elections. The Physician Payment Sunshine Act, enacted as part of PPACA, and its implementing regulations require 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, 2016, we had 432 employees. None of our employees is represented by a labor union. However, we have one employee in Belgium 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 federal, state, local and foreign 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 Securities and Exchange Commission, or 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.

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 anticipate that we will incur continued losses for at least the next few years. We cannot be certain that we will achieve or sustain profitability.

We have a history of losses and may continue to incur operating and net losses for the foreseeable future. For the fiscal years ended December 31, 2016, 2015 and 2014, we had net losses of \$22.3 million, \$24.5 million and \$22.2 million, respectively, and we had an accumulated deficit at December 31, 2016 of \$168.7 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. Even though we generate revenue from our T-SPOT.TB test, we anticipate that our operating losses will continue for the next few years as we continue to invest to grow our customer base and invest in research and development to expand our product portfolio. Because of the numerous risks and uncertainties associated with developing and commercializing diagnostic products, we are unable to predict the magnitude of these future losses. Our historic losses, combined with expected future losses, have had and will continue to have an adverse effect on our cash resources, shareholders' deficit and working capital. We expect our research and development expenses to be substantial for at least the next few years as we work to develop other product candidates based on our T-SPOT technology.

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We have not achieved profitability and our ability to become profitable depends upon our ability to generate revenue. In 2004, we began to generate revenue from the sale and marketing of our T-SPOT.TB test, but we may not be able to generate sufficient revenue to attain 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, 2016, we had cash and cash equivalents of \$59.1 million and working capital (total current assets less total current liabilities) of \$63.7 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.

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

We have experienced significant revenue growth in a relatively short period of time. We may not achieve similar growth rates in future periods. Investors should not rely on our operating results for any prior periods as an indication of our future operating performance. If we are unable to maintain adequate revenue growth, our financial results could suffer and our share price could decline.

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 cash flows and capital resources may be insufficient to make required payments on our indebtedness and future indebtedness.

On October 4, 2016, we entered into an agreement with MidCap Financial, or the MidCap agreement, that provides us with \$40 million in debt financing, comprised of both a term loan and a revolving line of credit. The MidCap agreement provides a term loan of \$30 million, which matures five years from closing. The term loan accrues 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 begins to amortize. The MidCap agreement also provides a revolving line of credit of up to \$10 million, which matures five years from closing. The revolving line of credit accrues interest at a rate of LIBOR plus 4.45%. Based on certain conditions, both the term loan and revolving line of credit may be increased by an additional \$10 million for a total of \$60 million. We did not borrow under the revolving line of credit during 2016.

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As of December 31, 2016, we had \$30.0 million of indebtedness under the MidCap agreement. Such indebtedness could have important consequences to us. For example, it could:

- make it difficult for us to satisfy our other debt obligations;
- make us more vulnerable to general adverse economic and industry conditions;
- limit our ability to obtain additional financing for working capital, capital expenditures, acquisitions and other general corporate requirements;
- expose us to interest rate fluctuations because the interest rate on the debt under the MidCap agreement is variable;
- require us to dedicate a portion of our cash flow from operations to payments on our debt, thereby reducing the availability of our cash flow for operations and other purposes;
- limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; and
- place us at a competitive disadvantage compared to competitors that may have proportionately less debt and greater financial resources.

In addition, our ability to make scheduled payments or refinance our obligations depends on our successful financial and operating performance, cash flows and capital resources, which in turn depend upon prevailing economic conditions and certain financial, business and other factors, many of which are beyond our control. These factors include, among others:

- economic and demand factors affecting our industry;
- pricing pressures;
- increased operating costs;
- competitive conditions; and
- other operating difficulties.

If our cash flows and capital resources are insufficient to fund our debt service obligations, we may be forced to reduce or delay capital expenditures, sell material assets or operations, obtain additional capital or restructure our debt. In the event that we are required to dispose of material assets or operations to meet our debt service and other obligations, the value realized on such assets or operations will depend on market conditions and the availability of buyers. Accordingly, any such sale may not, among other things, be for a sufficient dollar amount to fund our debt service obligations. Our obligations pursuant to the MidCap agreement are secured by first priority security interests in substantially all of our assets. The foregoing encumbrances may limit our ability to dispose of material assets or operations. We also may not be able to restructure our indebtedness on favorable economic terms, if at all.

We may incur additional indebtedness in the future, including pursuant to the MidCap agreement. Our incurrence of additional indebtedness would intensify the risks described above.

The MidCap agreement contains various covenants limiting the discretion of our management in operating our business.

The MidCap agreement contains, subject to certain carve-outs, various restrictive covenants that limit our management's discretion in operating our business. In particular, these instruments limit our ability to, among other things:

- incur additional debt;
- grant liens on assets;
- make investments, including capital expenditures;
- sell or acquire assets outside the ordinary course of business; and
- make fundamental business changes.

If we fail to comply with the restrictions in the MidCap agreement, a default may allow the creditors under the relevant instruments to accelerate the related debt and to exercise their remedies under these agreements, which will typically include the right to declare the principal amount of that debt, together with accrued and unpaid interest and other related amounts, immediately due and payable, to exercise any remedies the creditors may have to foreclose on assets that are subject to liens securing that debt and to terminate any commitments they had made to supply further funds.

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. There is no assurance that we will continue to generate revenues from this product, 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.

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 recently updated such that testing may now be required in fewer instances than under previous guidelines). If there are widespread testing policy changes that substantially reduce testing in the markets we serve, our business could be materially and adversely affected.

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.

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.

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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.

In our service offering, we also may face competition from commercial laboratories, including large national and regional laboratories, which may be able to offer access to TB testing. These laboratories may have perceived advantages over our solution, including phlebotomy services, established payor relationships and dedicated courier services. For example, as we seek to further penetrate the physicians' office segment of the U.S. market, we may find that physicians have established relationships with commercial laboratories that offer physicians additional services, such as phlebotomy, and a wider range of available laboratory tests that a physician may choose to order in addition to a TB test. Further, some commercial laboratories may be able to offer their services at lower cost to physicians' patients due to the reimbursement arrangements these laboratories may have established with third-party payors. These factors may make it difficult for us to convince physicians to use our test and service offering.

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, including those in the hospital and public health segments, 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.

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 Germany, Switzerland, France, Japan and China. 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 accounted for only about 10% of our total revenue for the year ended December 31, 2016, we currently rely in part, and may in the future more heavily rely, on obtaining third-party payment or reimbursement for our test. We or 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 our 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 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 T-SPOT.*TB*, T-SPOT.*CMV* and T-SPOT.*PRT* 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, 2016, sales to Fosun and through Riken together accounted for 29% of our total revenue, with Fosun accounting for 15% and Riken accounting for 14%. In the event that either 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.

We currently perform our tests for our service offering exclusively in one laboratory facility in the United States and one laboratory in the United Kingdom. If these or any future facilities or our equipment were 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 for our service offering in the United States exclusively in a single laboratory facility in Memphis, Tennessee, and in the United Kingdom exclusively in a single laboratory facility in Abingdon, England. In addition, our service offering for the testing for tick-borne diseases is performed exclusively in a single laboratory facility in Norwood, Massachusetts. If these or any future facilities were 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 laboratories 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 facilities are subject, including, for example, CLIA requirements in the United States. 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, 2016, we maintain insurance coverage totaling \$13.5 million against damage to our property and equipment and an additional \$56.6 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 LIS, our billing system, and our customer interfaces. Due to the sophisticated nature of the technology we use in our laboratories and our complex billing procedures, 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 billing 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.

We rely on courier delivery services to transport samples to our facilities for testing. If these delivery services are disrupted, our business and customer satisfaction could be negatively impacted.

Customers in the United States and the United Kingdom ship samples to us by air and ground express courier delivery service for testing in our Memphis, Tennessee, Norwood, Massachusetts and Abingdon, England facilities. If we suffer from disruptions in delivery service, whether due to bad weather, natural disaster, terrorist acts or threats, or for other reasons, we may be unable to provide timely services to customers or at all. As a result, such disruptions could materially and adversely affect our financial results and our reputation.

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, 2016, 42% 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 & 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 & ROW sales outside the United Kingdom and the European Union countries whose national currency is the Euro, or the Euro Zone, 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.

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, commonly referred to as “Brexit”, in which voters approved an exit from the European Union, or E.U. As a result of the referendum, it is expected that the British government will begin negotiating the terms of the U.K.’s future relationship with the E.U. Article 50 of the Treaty of the European Union, or Article 50, allows a member state to decide to withdraw from the E.U. in accordance with its own constitutional requirements. The formal process for leaving the E.U. will be triggered only when the U.K. delivers an Article 50 notice to the European Council, although informal negotiations around the terms of any exit may be held before such notice is given. On November 3, 2016, the U.K.’s High Court decided that the U.K. Government could not provide official notice to leave the E.U. without the U.K. Parliament’s approval. The U.K. Government appealed this decision, an appeal hearing was held before the U.K. Supreme Court, and the judgment followed on January 24, 2017 affirming the original decision. While the judgment is not expected to stop Brexit from occurring, it could affect the terms, nature and timetable of the exit.

Delivery of the Article 50 notice will start a two-year period for the U.K. to exit from the E.U., although this period can be extended with the unanimous agreement of the European Council. Without any such extension (and assuming that the terms of withdrawal have not already been agreed), the U.K.’s membership in the E.U. would end automatically on the expiration of that two-year period.

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.

Significant developments stemming from the recent U.S. presidential election could have a material adverse effect on us.

On January 20, 2017, Mr. Donald J. Trump was inaugurated as the president of the United States. As a presidential candidate, President Trump expressed concerns regarding existing trade agreements, such as the North American Free Trade Agreement (NAFTA), and raised the possibility of imposing significant increases on tariffs on goods imported into the United States, particularly from China and Mexico. President Trump has also indicated an intention to request Congress to make significant changes to U.S. tax laws, significant changes, replacement or elimination of the PPACA, and government negotiation/regulation of drug prices paid by government programs. Changes in U.S. social, political, regulatory and economic conditions or laws and policies governing the health care system and drug prices, 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 could adversely affect our operating results and our business.

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.

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We have completed three acquisitions since 2014. On July 31, 2014, we acquired substantially all of the assets of Boulder, a privately owned company developing immunology-based assays for autoimmune and inflammatory conditions/diseases. On July 1, 2016, we acquired substantially all of the assets of Imugen, a privately owned Massachusetts corporation specializing in the development and performance of testing for tick-borne diseases, including Lyme disease. On October 12, 2016, we acquired Immunetics, a privately owned Massachusetts corporation focused on developing specialized tests for infectious diseases, including tick-borne diseases, such as Lyme disease.

These acquisitions brought us additional product pipeline opportunities which we believe are well-suited to our growing commercial infrastructure, but there can be no assurance that we will be able to successfully develop and complete the development or commercialization of the products that we acquired in these acquisitions. Further, even if we are able to profitably commercialize the underlying product candidates, there is no guarantee that we will be able to do so before any competitors develop and commercialize similar products.

We could have difficulty in integrating acquired businesses, including the businesses of Boulder, Imugen and Immunetics, which may cause us not to realize expected revenue increases, cost savings, increases in geographic or product presence, and other projected benefits from these acquisitions. The integration of acquired businesses could result in the loss of key employees, disruption of our business or the business of the acquired company, or otherwise harm our ability to retain customers and employees or achieve the anticipated benefits of the acquisition. Time and resources spent on integration may also impair our ability to grow our existing businesses. Also, the negative effect of any financial commitments required by regulatory authorities or rating agencies in acquisitions or business combinations may be greater than expected.

In addition to our completed acquisitions, 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.

If we fail to successfully develop and complete our IPR&D program, our future operating results could be materially adversely impacted.

There can be no assurance that we will be able to successfully develop and complete the acquired IPR&D program and profitably commercialize the underlying product candidates before our competitors develop and commercialize similar products, or at all. Our acquired IPR&D assets include \$9.2 million for IPR&D acquired in conjunction with the Imugen acquisition and \$7.0 million for IPR&D acquired in conjunction with the Immunetics acquisition. If the acquired IPR&D program fails or is abandoned during development, then we may not realize the value we have estimated and recorded in our financial statements on the acquisition date, and we may also not recover the research and development investment made since the acquisition date to further develop that program. If such circumstances were to occur, our future operating results could be materially adversely impacted.

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.

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 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 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 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.

During the third quarter of 2015, the timeline for the development of an assay to inform decisions regarding biologic therapies that was acquired as part of the Boulder acquisition was changed due to delays in the completion of research studies. Based upon the changed timeline and the resulting impact on fair value, we recorded a non-cash IPR&D impairment charge of \$385,000.

We may incur additional non-cash charges related to impairments of our long-lived assets, including goodwill and indefinite-lived intangible assets. 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 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, 2016, our available U.S. federal net operating losses, or NOLs, totaled \$125.3 million and U.S. state loss carryforwards totaled \$112.5 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, as well as the initial public offering, or IPO, of our ordinary shares and an offering of additional ordinary shares that closed on February 4, 2015, 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.

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.

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.

If we are unable to comply with the requirements of CLIA and state laws governing clinical laboratories or if we are required to expend significant additional resources to comply with these requirements, the success of our business could be threatened.

HHS has classified our T-SPOT and tick-borne disease tests as high-complexity tests under CLIA. Under CLIA, personnel requirements for laboratories conducting high-complexity tests are more stringent than those applicable to laboratories performing less complex tests. As a result of these personnel requirements, we must employ more experienced or more highly educated personnel and additional categories of employees, which increases our operating costs. If we fail to meet CLIA requirements, HHS or state agencies could require us to cease some or all of the tests that we offer. Continued compliance with CLIA requirements may cause us to incur significant expenses and potentially lose revenue in doing so. Moreover, new interpretations of current regulations or future changes in regulations under CLIA may make it difficult or impossible for us to comply with our CLIA classification, which would significantly harm our business.

Many states in which our physician and laboratory clients are located, such as New York, have laws and regulations governing clinical laboratories that are more stringent than federal law and may apply to us even if we are not located, and do not perform tests, in that state. We may also be subject to additional licensing requirements as we expand our sales and operations into new geographic areas, which could impair our ability to pursue our growth strategy.

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, 2016, we had product liability insurance of \$12.4 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.

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

The U.S. federal privacy regulations limit use or disclosure of protected health information, without written patient authorization, to purposes of payment, treatment or healthcare operations (as defined under HIPAA) except for disclosures for various public policy purposes and other 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.

The privacy regulations establish a “floor” of minimum protection for patients as to their medical information and do not supersede state laws that are more stringent. Therefore, 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 Data Protection Directive 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.

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. We may face threats to our networks from unauthorized access, security breaches and other system disruptions. Despite our security measures, our infrastructure may be vulnerable to external or internal attacks. Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of sensitive or proprietary information. 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. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenue, regulatory actions or litigation. Any disruption of could also have a material adverse impact on our operations. To date, we have not experienced any material cybersecurity attacks.

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.

Our business arrangements with customers and third-party payors 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, physicians and third-party payors 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 third-party payors and 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.

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 may have 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, given the results of the November 2016 U.S. presidential election, 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, 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 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. In early 2017, Congress voted in favor of a budget resolution that will produce legislation that, if passed, would repeal certain aspects of the PPACA. Congress is also considering subsequent legislation to replace or repeal elements or all of the PPACA. In addition, there have been recent public announcements by members of Congress and the new presidential administration regarding their plans to repeal and replace the PPACA. Government and other regulatory oversight and future regulatory and government interference with the healthcare systems may 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.

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.

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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.

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. See “Legal Proceedings” for information regarding one such proceeding.

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, 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 recently 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.

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.

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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.

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.

We are eligible to be treated as an emerging growth company and we cannot be certain that the reduced disclosure requirements applicable to emerging growth companies will not make our ordinary shares less attractive to investors.

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act, or JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and our share price may be more volatile.

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We could be an emerging growth company for up to five years following our IPO, although certain circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds \$700.0 million as of any June 30 in any fiscal year before that time or if we have total annual gross revenue of \$1.0 billion or more during any fiscal year before that time, in which cases we would no longer be an emerging growth company as of the following December 31 or, if we issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Our share price may be volatile.

Like other early-stage 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.

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.

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 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, based upon the Beneficial Ownership Table filed with the 2016 Proxy Statement, as of April 25, 2016, our executive officers, directors, and 5% or greater shareholders held of record approximately 31% 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.

We incur increased costs as a result of being a public company whose ordinary shares are publicly traded in the United States and our management must devote substantial time to public company compliance programs.

As a public company, we have incurred and will continue to incur significant legal, insurance, accounting and other expenses that we did not incur as a private company. We intend to continue to invest resources to comply with evolving laws, regulations and standards, and this investment will result in increased general and administrative expenses and may divert management's time and attention. If our efforts to comply with new laws, regulations and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and our business may be harmed. Our insurance costs have increased, particularly for directors and officers liability insurance. Such costs may further increase in the future, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These factors could also make it more difficult for us to attract and retain qualified members of our Board of Directors, particularly to serve on our audit committee and remuneration committee, and qualified executive officers.

Pursuant to Section 404 of the Sarbanes-Oxley Act, or Section 404, we are required to furnish a report by our management on our internal control over financial reporting, and, once we cease to be an emerging growth company, will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. We cannot assure you that there will not be material weaknesses or significant deficiencies in our internal controls in the future.

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. You may also not be able to resell your shares at or above the price you 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.

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.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our U.K. corporate headquarters and operations, including our laboratory facility, are located in Abingdon, England, where we currently lease approximately 9,700 square feet of office space, 2,800 square feet of manufacturing space, 2,100 square feet of laboratory space, and 6,400 square feet of storage/warehouse space. The leases on these facilities expire in 2019, with the exception of the storage/warehouse space which expires in 2025. Our current rents under these leases are \$370,000 annually for the office, \$103,000 annually for the manufacturing space, \$83,000 annually for the laboratory, and \$72,000 annually for the storage/warehouse space, each of which are subject to change.

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. Our main U.S. laboratory facility is located in Memphis, Tennessee, where we currently lease approximately 35,000 square feet of space. The lease on this facility expires in 2021. Our current rent under this lease is \$150,000 annually, subject to annual increases. The two laboratory facilities acquired in 2016 are located in Norwood and Boston, Massachusetts. We currently lease approximately 22,000 square feet of space in Norwood and approximately 18,000 square feet in Boston. The Norwood lease expires in 2021, while the Boston lease expires in 2018. Our current rent under the Norwood lease is \$412,000 annually, subject to annual increases. Our current rent under the Boston lease is \$263,000 annually.

We believe that our current facilities are suitable and adequate to meet our current needs and that suitable additional or substitute space will be available to accommodate future growth of our business.

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 alleges that the defendants’ manufacture, sale and/or use of the QuantiFERON-TB Gold test infringes patents owned by Oxford Immunotec Limited. Trial is set for January 16, 2018. We can provide no assurance as to the likely outcome of the litigation.

Item 4. Mine Safety Disclosures

Not applicable.

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

Our 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, 2016		Year ended December 31, 2015	
	High	Low	High	Low
First quarter	\$ 12.13	\$ 8.45	\$ 15.04	\$ 11.36
Second quarter	11.91	8.50	14.85	11.63
Third quarter	12.99	7.73	14.99	10.41
Fourth quarter	15.18	11.88	14.25	11.08

Shareholders

On February 1, 2017, 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 21, 2017, the last reported sale price per share of our ordinary shares on The NASDAQ Global Market was \$13.45.

Dividends

We have never declared or paid cash dividends on our ordinary shares. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business and we 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.

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.

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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.

(in thousands, except share and per share data)	Year ended December 31,				
	2016	2015	2014	2013(1)	2012
Consolidated statement of operations data:					
Revenue	\$ 86,078	\$ 62,782	\$ 49,505	\$ 38,784	\$ 20,685
Cost of revenue	39,472	29,544	24,009	18,600	12,424
Gross profit	46,606	33,238	25,496	20,184	8,261
Operating expenses:					
Research and development	13,881	10,381	6,961	2,146	1,947
Sales and marketing	34,964	30,402	25,487	13,270	11,177
General and administrative	23,181	16,010	14,837	12,119	8,068
Change in fair value of contingent purchase price consideration	(1,208)	202	72	—	—
Intangible assets impairment charges	1,765	419	—	—	—
Total operating expenses	72,583	57,414	47,357	27,535	21,192
Loss from operations	(25,977)	(24,176)	(21,861)	(7,351)	(12,931)
Other expense	(146)	(156)	(159)	(1,221)	(2,103)
Loss before income taxes	(26,123)	(24,332)	(22,020)	(8,572)	(15,034)
Income tax benefit (expense)	3,774	(146)	(154)	(92)	151
Net loss	<u>\$ (22,349)</u>	<u>\$ (24,478)</u>	<u>\$ (22,174)</u>	<u>\$ (8,664)</u>	<u>\$ (14,883)</u>
Net loss per share attributable to ordinary shareholders, basic and diluted	<u>\$ (1.00)</u>	<u>\$ (1.12)</u>	<u>\$ (1.28)</u>	<u>\$ (2.26)</u>	<u>\$ (8.44)</u>
Weighted-average shares used to compute net loss attributable to ordinary shareholders, basic and diluted	<u>22,353,713</u>	<u>21,781,933</u>	<u>17,310,148</u>	<u>3,830,837</u>	<u>1,763,728</u>
Supplemental financial metric:					
Adjusted EBITDA (2)	<u>\$ (18,469)</u>	<u>\$ (18,167)</u>	<u>\$ (17,664)</u>	<u>\$ (6,008)</u>	<u>\$ (12,131)</u>

- (1) Net loss includes \$1.9 million of accounting and auditing costs related to our registration statement on Form S-1, filed in connection with our IPO.
- (2) Adjusted EBITDA is a non-Generally Accepted Accounting Principles, or non-GAAP, financial measure that we calculate as profit (loss), adjusted for tax benefit (expense), interest expense, net, depreciation and amortization, share-based compensation, unrealized exchange fluctuations, loss on change in fair value of warrants, loss on change in fair value of derivative instrument, change in fair value of contingent purchase price consideration, and intangible assets impairment charges. We believe that Adjusted EBITDA provides useful information to investors and analysts in understanding and evaluating our operating results in the same manner as our management and Board of Directors. Our presentation of Adjusted EBITDA is not made in accordance with U.S. GAAP, and our computation of Adjusted EBITDA may vary from others in the industry. Our use of Adjusted EBITDA 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. For example, Adjusted EBITDA does not reflect the impact of earnings or charges resulting from matters that we consider not to be indicative of our ongoing operations.

	As of December 31,				
	2016	2015	2014	2013	2012
Consolidated Balance Sheet Data:					
Cash and cash equivalents	\$ 59,110	\$ 83,715	\$ 50,165	\$ 76,494	\$ 12,578
Total assets	124,012	109,852	73,849	92,744	25,483
Total liabilities	51,048	17,160	13,240	11,992	8,534
Total shareholders' equity	72,964	92,692	60,609	80,752	16,949
Shares outstanding:					
Preferred ordinary shares	—	—	—	—	7,301,371
Ordinary shares	22,635,431	22,549,488	17,614,650	17,255,267	2,153,974

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 loss to Adjusted EBITDA ⁽¹⁾
(unaudited)

(in thousands)	Year Ended December 31,				
	2016	2015	2014	2013	2012
Reconciliation of net loss to adjusted EBITDA					
Net loss	\$ (22,349)	\$ (24,478)	\$ (22,174)	\$ (8,664)	\$ (14,883)
Income tax (benefit) expense	(3,774)	146	154	92	(151)
Interest expense, net	864	67	52	328	1,477
Depreciation and amortization	3,094	2,142	1,742	1,101	801
EBITDA	(22,165)	(22,123)	(20,226)	(7,143)	(12,756)
Reconciling items:					
Share-based compensation expense	5,019	3,485	2,521	140	79
Unrealized exchange (gains) losses	(1,880)	(150)	(53)	155	546
Loss on change in fair value of warrants	—	—	22	279	—
Loss on change in fair value of derivative instrument	—	—	—	561	—
Change in fair value of contingent purchase price consideration	(1,208)	202	72	—	—
Intangible asset impairment charges	1,765	419	—	—	—
Adjusted EBITDA	\$ (18,469)	\$ (18,167)	\$ (17,664)	\$ (6,008)	\$ (12,131)

(1) EBITDA and Adjusted EBITDA are non-GAAP measures that we calculate as net 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.

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."

Overview

We are a global, high-growth diagnostics company focused on developing and commercializing proprietary tests for under-served immune-regulated conditions. Our current product lines and development activities principally focus on four areas: infectious diseases, transplantation, autoimmune and inflammatory disease and immune-oncology. We believe these areas are particularly 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. These immune-regulated conditions also tend to be characterized by wide variation in presentation and progression and often require expensive therapies, making diagnostic tests that can better categorize patients and inform treatment pathways particularly useful and cost-effective. Lastly, we believe these conditions to be under-served as the industry lacks the appropriate techniques to prosecute the immune responses which are driving these conditions.

On July 1, 2016, we acquired substantially all of the assets of Imugen, Inc., or Imugen, a privately owned Massachusetts corporation specializing in developing and commercializing proprietary tests for tick-borne diseases, including Lyme disease.

On October 12, 2016, we acquired Immunetics, Inc., or Immunetics, a privately owned Massachusetts corporation focused on developing specialized tests for infectious diseases, including tick-borne diseases, such as Lyme disease. Total consideration consisted of \$6 million in cash and up to an additional \$6 million in cash payable on the achievement of certain revenue thresholds and pipeline related milestones over the next three years.

Our first product, the T-SPOT[®].TB test, is used to test for tuberculosis, or TB, infection and leverages our proprietary 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. Interferon-gamma release assays, or IGRAs, such as our T-SPOT.TB test have been included in clinical guidelines for TB testing in at least 34 countries, including the United States, several European countries 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 and Germany. We have also established the cost-effectiveness of our test in several published studies.

Our second product line is a range of assays for tick-borne diseases, such as Lyme disease, obtained through the acquisitions of Imugen and Immunetics, in 2016. Tick-borne disease is the collective name for diseases passed to humans through the bite of an infected tick. The most prevalent and well known tick-borne disease is Lyme disease, but there are others such as anaplasmosis, ehrlichiosis, and babesiosis. If left unrecognized, and therefore untreated, they may go on to cause significant downstream morbidity, including in rare cases death. Our diagnostic tests for tick-borne infections include multiple proprietary laboratory developed tests, or LDTs, offered from our Clinical and Laboratory Improvement Amendments, or CLIA, certified and College of American Pathologists, or CAP, accredited laboratory in Massachusetts and an FDA cleared test kit utilizing the C6 peptide, which is a marker specific to Lyme disease. Our C6 Lyme ELISA kit is also CE marked in the European Union. Our tick-borne disease tests utilize molecular methods (such as polymerase chain reaction) and techniques to prosecute the immune system, and offer advantages over current tests and are widely reimbursed in the U.S. using existing codes on fee schedules.

Our third product line is a series of assays for use in blood screening, building upon our expertise in tick-borne disease. The parasite *Babesia microti* which causes babesiosis can be transmitted through the transfusion of infected blood, as well as by the bite of an infected tick. We are developing three assays for use in screening the U.S. blood supply for *Babesia microti*. We have submitted biological license applications for these three assays and they are currently under review by the FDA.

Babesiosis is a tick-borne disease characterized by a wide spectrum of clinical manifestations that range from asymptomatic to severe acute or even fatal illness. While the disease is generally mild to moderate in children and young healthy adults, it is more severe in neonates, the elderly and immunocompromised individuals such as those undergoing treatment for cancer. Babesiosis is predominately caused by a parasite called *Babesia microti*. While it is primarily transmitted through a tick bite, babesiosis can also be transmitted by blood transfusion. In fact, transfusion-transmitted babesiosis is responsible for the highest percentage (38%) of transfusion-related infectious fatalities reported to the FDA in transfusion recipients and *Babesia microti* is the highest ranking pathogen in the U.S. transmitted by blood transfusion for which no donor screening is available. The transmission risk of *Babesia microti* is comparable to the transmission risk of HIV, HBV, and HCV prior to the implementation of routine blood screening programs for these pathogens. Screening for *Babesia microti*, therefore, has become a priority for the FDA.

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Our T-SPOT. *CMV* and T-SPOT. *PRT* tests are part of our fourth product line focused on the transplantation market. Both tests utilize our T-SPOT technology platform and are laboratory developed tests, or LDTs, performed in our CLIA certified, CAP accredited laboratory in Tennessee. Both the T-SPOT. *CMV* and T-SPOT. *PRT* tests are CE marked in the European Union. The T-SPOT. *CMV* test measures the strength of a patient's cellular immune response to CMV specific antigens and provides information that may be useful in informing management strategies of patients at risk of CMV infection and disease, such as transplant patients. The T-SPOT. *PRT* test assesses a solid organ transplant candidate's T cell response to foreign tissue, or alloreactivity, and may help clinicians identify patients at increased risk of T cell mediated rejection post-transplant. We continue to take a measured approach to market introduction of these tests as we await final results of our two pivotal clinical studies involving these tests.

In addition to our existing product lines, we continue to pursue development programs targeting other immune-regulated conditions, as well as applications of our T-SPOT technology platform in immune-oncology. Product development activities are inherently uncertain, and there can be no assurance that we will be able to obtain regulatory body clearance to market any of our products, or if we obtain clearances that we will successfully commercialize any 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.

We have incurred significant losses from inception and as of December 31, 2016 had an accumulated deficit of \$168.7 million. We anticipate that our operating losses will continue for the next few years as we continue to invest to grow our customer base and invest in research and development to expand our product portfolio. Our revenue for the year ended December 31, 2016 was \$86.1 million, for the year ended December 31, 2015 was \$62.8 million, and for the year ended December 31, 2014 was \$49.5 million. Our net loss for the year ended December 31, 2016 was \$22.3 million, for the year ended December 31, 2015 was \$24.5 million, and for the year ended December 31, 2014 was \$22.2 million.

Financial operations overview

Revenue

We generate revenue 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 and accounted for more than 91 % of total revenue in 2016. In addition, U.S. results for 2016 include revenue from assays for tick-borne diseases, such as Lyme disease, obtained through our acquisitions of Imugen and Immunetics in 2016.

Revenue mix

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 established clinical testing laboratories in the United States and the United Kingdom, where we perform our T-SPOT. *TB* test on samples sent to us by customers. In these markets, we have found that many of our customers prefer to send samples to us rather than perform their own analysis on-site.

Our U.S. business derived 96% of our revenue from our service offering, as opposed to kit sales, for each of the years ended December 31, 2016, 2015 and 2014. These results reflect our experience that our U.S. customers prefer to send IGRA tests out for processing and analysis rather than run them in-house. For the majority of our U.S. customers in the hospital and public health segments, TB testing programs are funded primarily from institutional budgets. We receive payment from these customers according to our pre-negotiated prices. For other segments of the U.S. market (notably, for example, the physicians' office segment) third-party reimbursement is often available to cover the cost of our T-SPOT. *TB* test. In addition, U.S. results for 2016 include revenue from operations acquired from Imugen, which is 100% U.S. service revenue, and from Immunetics, which is 100% product revenue.

Outside the United States, we derived 94%, 92% and 91% of our revenue from the sale of our *in vitro* diagnostic kits and associated accessories for the years ended December 31, 2016, 2015 and 2014, respectively. For the majority of our customers outside the United States, 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 thousands)	Year ended December 31,		
	2016	2015	2014
Revenue			
Product	\$ 36,430	\$ 30,207	\$ 25,407
Service	49,648	32,575	24,098
Total revenue	<u>\$ 86,078</u>	<u>\$ 62,782</u>	<u>\$ 49,505</u>

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Revenue by indication

With the acquisitions of Imugen and Immunetics, we evolved from a single-product company to a multi-product company in 2016. By indication, total revenues were as summarized in the table below.

(in thousands)	Year ended December 31,		
	2016	2015	2014
Revenue			
Tuberculosis	\$ 78,636	\$ 62,782	\$ 49,505
Tick-borne disease and other	7,442	—	—
Total revenue	<u>\$ 86,078</u>	<u>\$ 62,782</u>	<u>\$ 49,505</u>

Revenue by geography

We have a direct sales force in the United States, certain European countries and Japan and market development personnel in China and 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. We intend to expand our sales force globally and establish additional distributor relationships outside of our direct markets to better access these international markets.

The following table reflects total revenue by geography (United States, Europe and rest of world, or Europe and ROW, and Asia) and as a percentage of total product revenue, based on the billing address of our customers. Revenue from operations acquired from Imugen and Immunetics are included in United States revenue from their respective acquisition dates.

(in thousands, except percentages)	Year ended December 31,					
	2016		2015		2014	
Revenue						
United States	\$ 49,462	58%	\$ 31,362	50%	\$ 22,537	46%
Europe & ROW	6,988	8%	7,067	11%	7,219	14%
Asia	29,628	34%	24,353	39%	19,749	40%
Total revenue	<u>\$ 86,078</u>	<u>100%</u>	<u>\$ 62,782</u>	<u>100%</u>	<u>\$ 49,505</u>	<u>100%</u>

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 and, in 2015 and 2014, the U.S. medical device excise tax. The U.S. Consolidated Appropriations Act of 2016, signed into law on December 18, 2015, includes a two year moratorium on the medical device excise tax imposed by Internal Revenue Code section 4191. Thus, the medical device excise tax does not apply to our U.S. sales during the period from January 1, 2016 through December 31, 2017.

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.

During the years ended December 31, 2016, 2015 and 2014, our cost of revenue represented 46%, 47% and 48%, respectively, of our total revenue.

(in thousands)	Year ended December 31,		
	2016	2015	2014
Cost of revenue			
Product	\$ 13,956	\$ 13,297	\$ 11,225
Service	25,516	16,247	12,784
Total cost of revenue	<u>\$ 39,472</u>	<u>\$ 29,544</u>	<u>\$ 24,009</u>

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 54%, 53% and 52%, respectively, for the years ended December 31, 2016, 2015 and 2014. All cost of revenue from operations acquired from Imugen and Immunetics are reflected in service cost of revenue and product cost of revenue, respectively.

Research and development expenses

Our research and development efforts have historically focused on developing multiple new diagnostic tests that use our quantitative T cell measurement technology, including assays that may help transplant physicians better manage patients at risk of rejection and infection. With the acquisition of Boulder Diagnostics, Inc., or Boulder, in July 2014, we expanded our research and development efforts to include the development of immunology-based assays for autoimmune and inflammatory conditions. On July 1, 2016, we completed our acquisition of substantially all of the assets of Imugen, a privately owned Massachusetts corporation focused on the development and performance of tests for tick-borne diseases. Additionally, on October 12, 2016, we acquired Immunetics, a Massachusetts based diagnostics company focused on developing specialized tests for infectious diseases, including tick-borne diseases, such as Lyme disease.

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 have supported the continued growth of our T-SPOT.TB business and expanded the team focused on the development of new products through management of clinical trial programs. In addition, we are expanding our research and development efforts in the United Kingdom and in the United States. We expense all research and development costs as incurred.

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During the years ended December 31, 2016, 2015 and 2014, our research and development expenses represented 16%, 17% and 14%, respectively, of our total revenue. Although research and development expense, as a percentage of revenue, has declined in 2016 compared to 2015, spending has increased in absolute terms primarily related to clinical trials, including the PROTECT clinical trial, which is a pivotal clinical trial designed to demonstrate the clinical value of our T-SPOT.CMV and T-SPOT.PRT tests, and the REACT clinical trial, which focuses on the clinical value of our T-SPOT.CMV test for stem cell transplant patients. The increases also include development project expenses related to our transplant program and the hiring of personnel in the United States to support development programs and projects acquired in the Boulder, Imugen and Immunetics acquisitions.

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, 2016, 2015 and 2014, our sales and marketing expenses represented 41%, 49% and 51%, respectively, of our total revenue. Although sales and marketing expense, as a percentage of revenue, has declined in 2016 compared to 2015, spending has increased in absolute terms as we have expanded our sales force, business development activities, geographic presence and marketing and medical education programs to increase awareness and adoption of our current T-SPOT.TB and tick-borne disease tests and future products.

General and administrative expenses

Our general and administrative expenses include costs for our executive, accounting and 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. We expense all general and administrative expenses as incurred.

During the years ended December 31, 2016, 2015 and 2014, our general and administrative expenses represented 27%, 26% and 30%, respectively, of our total revenue. Although general and administrative expense, as a percentage of revenue, has remained relatively flat in 2016 compared to 2015, spending has increased in absolute terms largely as a result of higher salary and other employee related expenses and professional fees.

General and administrative expenses for 2016 included \$475,000 in legal and accounting fees related to our July 1, 2016 acquisition of Imugen and \$655,000 in legal and accounting fees related to our October 12, 2016 acquisition of Immunetics.

Change in fair value of contingent purchase price consideration

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 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 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. The charge of \$202,000 in 2015 related to the change in the fair value of contingent purchase price consideration resulting from the acquisition of Boulder in July 2014.

Intangible assets impairment charges

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 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. The charge in 2015 mainly related to the timeline for the development of an assay to inform decisions regarding biologic therapies that was acquired as part of the Boulder acquisition that was changed due to delays in the completion of research studies. Based upon the changed timeline and the resulting impact on fair value, we recorded a non-cash IPR&D impairment charge of \$385,000.

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Other income (expense)

Other income (expense) includes interest expense, net, foreign exchange gains/(losses) and other income and expense items.

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, Yen and the Yuan, depending on the entity.

Results of operations

Comparison of years ended December 31, 2016 and 2015

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.

(in thousands, except percentages)	Year ended December 31,				Change	
	2016		2015		Amount	%
	Amount	% of revenue	Amount	% of revenue		
Revenue:						
Product	\$ 36,430	42%	\$ 30,207	48%	\$ 6,223	21%
Service	49,648	58%	32,575	52%	17,073	52%
Total revenue	86,078	100%	62,782	100%	23,296	37%
Cost of revenue:						
Product	13,956	16%	13,297	21%	659	5%
Service	25,516	30%	16,247	26%	9,269	57%
Total cost of revenue	39,472	46%	29,544	47%	9,928	34%
Gross profit	46,606	54%	33,238	53%	13,368	40%
Operating expenses:						
Research and development	13,881	16%	10,381	17%	3,500	34%
Sales and marketing	34,964	41%	30,402	48%	4,562	15%
General and administrative	23,181	27%	16,010	26%	7,171	45%
Change in fair value of contingent purchase price consideration	(1,208)	(1)%	202	0%	(1,410)	(698)%
Intangible assets impairment charges	1,765	2%	419	1%	1,346	321%
Total operating expenses	72,583	84%	57,414	91%	15,169	26%
Loss from operations	(25,977)	(30)%	(24,176)	(39)%	(1,801)	7%
Interest expense, net	(864)	(1)%	(67)	(0)%	(797)	1,190%
Foreign exchange gains (losses)	1,364	2%	(143)	(0)%	1,507	(1,054)%
Other (expense) income	(646)	(1)%	54	0%	(700)	(1,296)%
Loss before income taxes	(26,123)	(30)%	(24,332)	(39)%	(1,791)	7%
Income tax benefit (expense)	3,774	4%	(146)	(0)%	3,920	2,685%
Net loss	\$ (22,349)	(26)%	\$ (24,478)	(39)%	\$ 2,129	(9)%

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Revenue

Revenue increased by 37% to \$86.1 million for the year ended December 31, 2016 compared to \$62.8 million for the same period in 2015. This increase in revenue was due to an increase in volumes across all regions where we sell our T-SPOT.TB tests and to the addition of our tick-borne disease tests.

U.S. revenue grew by 58%, to \$49.5 million for the year ended December 31, 2016, compared to the same period in 2015, driven by T-SPOT.TB test growth of \$5.8 million from the addition of new customers and \$4.9 million from existing customers. In addition, revenue for the year ended December 31, 2016 included tick-borne and other revenue of \$7.4 million.

Asia revenue grew by 22%, to \$29.6 million, compared to the same period in 2015, due primarily to an increase in volumes that led to higher revenue in Japan and China. On a non-Generally Accepted Accounting Principles, or non-GAAP, constant currency basis, revenue for Asia would have increased by 15%. Europe & ROW revenue decreased by 1%, to \$7.0 million, compared to the same period in 2015, due primarily to changes in currency rates. On a non-GAAP constant currency basis, Europe and ROW revenue would have increased by 5% in 2016 compared to 2015.

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:

(in thousands, except percentages)	Year ended December 31,		Change	
	2016	2015	Amount	%
Revenue				
Product	\$ 36,430	\$ 30,207	\$ 6,223	21%
Service	49,648	32,575	17,073	52%
Total revenue	<u>\$ 86,078</u>	<u>\$ 62,782</u>	<u>\$ 23,296</u>	<u>37%</u>

By indication, total revenues were:

(in thousands, except percentages)	Year ended December 31,		Change	
	2016	2015	Amount	%
Revenue				
Tuberculosis	\$ 78,636	\$ 62,782	\$ 15,854	25%
Tick-borne disease and other	7,442	—	7,442	N/M
Total revenue	<u>\$ 86,078</u>	<u>\$ 62,782</u>	<u>\$ 23,296</u>	<u>37%</u>

By geography, total revenues were:

(in thousands, except percentages)	Year ended December 31,		Change	
	2016	2015	Amount	%
Revenue				
United States	\$ 49,462	\$ 31,362	\$ 18,100	58%
Europe & ROW	6,988	7,067	(79)	(1)%
Asia	29,628	24,353	5,275	22%
Total revenue	<u>\$ 86,078</u>	<u>\$ 62,782</u>	<u>\$ 23,296</u>	<u>37%</u>

Cost of revenue and gross margin

Cost of revenue increased by 34% to 39.5 million for the year ended December 31, 2016 from \$29.5 million in the same period in 2015. This increase in cost of revenue was due to the 25% increase in the volume of kits sold and a 33% increase in the volume of TB tests performed by our laboratory in the United States. In addition, U.S. cost of revenue for the year ended December 31, 2016 included \$4.1 million of cost of revenue from testing for tick-borne diseases. Gross margin for 2016 increased to 54% from 53% for 2015. The gross margin improvement was attributable to a reduction in material costs per test and efficiency gains from increased volume in our manufacturing operations and service laboratories, partially offset by increased labor costs and lower margin on tick-borne testing.

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(in thousands, except percentages)	Year ended December 31,		Change	
	2016	2015	Amount	%
Cost of revenue				
Product	\$ 13,956	\$ 13,297	\$ 659	5%
Service	25,516	16,247	9,269	57%
Total cost of revenue	<u>\$ 39,472</u>	<u>\$ 29,544</u>	<u>\$ 9,928</u>	<u>34%</u>

Research and development expenses

Research and development expenses increased by 34% to \$13.9 million for the year ended December 31, 2016 from \$10.4 million for the same period in 2015. Salary and other employee related expenses increased \$1.7 million. In addition, clinical studies costs increased \$1.5 million in the year ended December 31, 2016 compared to the same period in 2015 and primarily related to the cost of clinical studies related to our transplant programs. As a percentage of total revenue, research and development expenses decreased to 16% for the year ended December 31, 2016 from 17% for the same period in 2015.

Sales and marketing expenses

Sales and marketing expenses increased 15% to \$35.0 million for the year ended December 31, 2016 from \$30.4 million for the same period in 2015. The increase largely resulted from salary and other employee related expenses, which increased \$4.2 million in the year ended December 31, 2016 compared to the same period in 2015. The increase reflects an increase in sales personnel and in personnel-related costs for commissions on increased sales. As a percentage of total revenue, sales and marketing expenses decreased to 41% for the year ended December 31, 2016 from 48% for the same period in 2015.

General and administrative expenses

General and administrative expenses increased by 45% to \$23.2 million for the year ended December 31, 2016 from \$16.0 million for the same period in 2015. The increase in general and administrative expenses included increases of \$3.6 million in salary and other employee related expenses, \$2.5 million in professional fees and \$461,000 for improvements in our information technology infrastructure. As a percentage of total revenue, general and administrative expenses increased to 27% for the year ended December 31, 2016 from 26% for the same period in 2015.

Change in fair value of contingent purchase price consideration

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 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 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.

Intangible assets impairment charges

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 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. The charge in 2015 mainly related to the timeline for the development of an assay to inform decisions regarding biologic therapies that was acquired as part of the Boulder acquisition that was changed due to delays in the completion of research studies. Based upon the changed timeline and the resulting impact on fair value, we recorded a non-cash IPR&D impairment charge of \$385,000.

Interest expense, net

Interest expense, net was \$864,000 for the year ended December 31, 2016, compared to \$67,000 in the same period in 2015. The increase in interest expense, net in 2016 mainly related to our October 4, 2016 agreement with MidCap Financial, or the MidCap agreement, that provides us with \$40 million in debt financing, comprised of both a term loan and a revolving line of credit. The MidCap agreement provides us with a term loan of \$30 million, which matures five years from closing. The term loan accrues 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 begins to amortize. The MidCap agreement also provides us with a revolving line of credit of up to \$10 million, which matures five years from closing. The revolving line of credit accrues interest at a rate of LIBOR plus 4.45%. Based on certain conditions, both the term loan and revolving line of credit may be increased by an additional \$10 million for a total of \$60 million. We did not borrow under the revolving line of credit during 2016.

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Foreign exchange gains (losses)

We recorded foreign exchange gains of \$1.4 million for the year ended December 31, 2016, 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, 2015, we recorded foreign exchange losses of \$143,000, as a net result of the U.S. Dollar denominated bank accounts, accounts receivable and accounts payable reflected on the books of Oxford Immunotec Limited. We are exposed to foreign exchange rate risk because we currently operate in three major regions of the world: the United States, Europe & ROW and Asia, and our revenue is denominated in multiple currencies. Approximately 58% of our sales were in the United States, which are denominated in U.S. Dollars. Sales in China 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 U.K. 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 and China.

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) income

Other (expense) income was expense of \$646,000 for the year ended December 31, 2016, which included a fixed asset impairment charge of \$306,000, compared to income of \$54,000 in the same period in 2015.

Comparison of years ended December 31, 2015 and 2014

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.

(in thousands, except percentages)	Year ended December 31,				Change	
	2015		2014		Amount	%
	Amount	% of revenue	Amount	% of revenue		
Revenue:						
Product	\$ 30,207	48%	\$ 25,407	51%	\$ 4,800	19%
Service	32,575	52%	24,098	49%	8,477	35%
Total revenue	62,782	100%	49,505	100%	13,277	27%
Cost of revenue:						
Product	13,297	21%	11,225	23%	2,072	18%
Service	16,247	26%	12,784	26%	3,463	27%
Total cost of revenue	29,544	47%	24,009	48%	5,535	23%
Gross profit	33,238	53%	25,496	52%	7,742	30%
Operating expenses:						
Research and development	10,381	17%	6,961	14%	3,420	49%
Sales and marketing	30,402	48%	25,487	51%	4,915	19%
General and administrative	16,010	26%	14,837	30%	1,173	8%
Change in fair value of contingent purchase price consideration	202	0%	72	0%	130	181%
Intangible assets impairment charges	419	1%	—	0%	419	N/A
Total operating expenses	57,414	91%	47,357	96%	10,057	21%
Loss from operations	(24,176)	(39)%	(21,861)	(44)%	(2,315)	11%
Interest expense, net	(67)	0%	(52)	0%	(15)	29%
Foreign exchange losses	(143)	0%	(352)	(1)%	209	(59)%
Other income	54	0%	245	0%	(191)	(78)%
Loss before income taxes	(24,332)	(39)%	(22,020)	(44)%	(2,312)	10%
Income tax expense	146	0%	154	0%	(8)	(5)%
Net loss	<u>\$ (24,478)</u>	<u>(39)%</u>	<u>\$ (22,174)</u>	<u>(45)%</u>	<u>\$ (2,304)</u>	<u>10%</u>

Revenue

Revenue increased by 27% to \$62.8 million for the year ended December 31, 2015 compared to \$49.5 million for the same period in 2014. This increase in revenue was due to an increase in volumes across all regions where we sell our T-SPOT.TB test. U.S. revenue grew by 39%, to \$31.4 million for the year ended December 31, 2015, compared to the same period in 2014, driven by growth of \$5.4 million from the addition of new customers and \$3.4 million from existing customers. Asia revenue grew by 23%, to \$24.4 million, compared to the same period in 2014, due primarily to higher revenue in Japan and China. On a constant currency basis, revenue for Asia would have increased by 33%. Europe & ROW revenue decreased by 2%, to \$7.1 million, compared to the same period in 2014, due primarily to changes in currency rates. On a constant currency basis, Europe & ROW revenue would have increased by 10% in 2015 compared to 2014.

(in thousands, except percentages)	Year ended December 31,		Change	
	2015	2014	Amount	%
Revenue				
Product	\$ 30,207	\$ 25,407	\$ 4,800	19%
Service	32,575	24,098	8,477	35%
Total revenue	\$ 62,782	\$ 49,505	\$ 13,277	27%

(in thousands, except percentages)	Year ended December 31,		Change	
	2015	2014	Amount	%
Revenue				
United States	\$ 31,362	\$ 22,537	\$ 8,825	39%
Europe & ROW	7,067	7,219	(152)	(2)%
Asia	24,353	19,749	4,604	23%
Total revenue	\$ 62,782	\$ 49,505	\$ 13,277	27%

Cost of revenue and gross margin

Cost of revenue increased by 23% to \$29.5 million for the year ended December 31, 2015 from \$24.0 million in the same period of 2014. This increase in cost of revenue was due to the increased volume of kits sold and an increase in volume of tests performed by our laboratories in the United States and the United Kingdom. Gross margin for 2015 increased to 52.9% from 51.5% for 2014. The gross margin improvement was attributable to a reduction in material costs per test and efficiency from increased volume in our manufacturing operations and service laboratories, partially offset by the impact of foreign currency exchange rate changes and increased share-based compensation expense in 2015 compared to 2014.

(in thousands, except percentages)	Year ended December 31,		Change	
	2015	2014	Amount	%
Cost of revenue				
Product	\$ 13,297	\$ 11,225	\$ 2,072	18%
Service	16,247	12,784	3,463	27%
Total cost of revenue	\$ 29,544	\$ 24,009	\$ 5,535	23%

Research and development expenses

Research and development expenses increased by 49% to \$10.4 million for the year ended December 31, 2015 from \$7.0 million for the same period in 2014. This increase reflected the fact that in 2014 we were just beginning to ramp-up our research and development activities following completion of our IPO in late 2013. The increased spending primarily related to development project expenses for our transplant program and to the hiring of personnel in the United States to support development programs. In addition, with the acquisition of Boulder in the third quarter of 2014, we expanded our research efforts to include assays for Lyme disease and gout.

Salary costs increased \$2.1 million in 2015 compared to 2014 due to the expansion of our research and development teams, and the cost of clinical studies increased \$1.1 million. As a percentage of total revenue, research and development expenses increased to 17% for the year ended December 31, 2015 from 14% for the same period in 2014.

Sales and marketing expenses

Sales and marketing expenses increased 19% to \$30.4 million for the year ended December 31, 2015 from \$25.5 million for the same period in 2014. The increase reflected additional sales, marketing, and customer service personnel and the expansion of marketing programs. Salary costs increased \$5.3 million in 2015 compared to 2014. In addition, travel costs increased \$442,000, and symposia costs increased \$309,000. These increases were partially offset by an \$815,000 decrease in market research costs, reflecting one-time market research studies completed in 2014, and a \$624,000 decrease in recruiting and hiring costs. As a percentage of total revenue, sales and marketing expenses decreased to 48% for the year ended December 31, 2015 from 51% for the same period in 2014.

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General and administrative expenses

General and administrative expenses increased by 8% to \$16.0 million for the year ended December 31, 2015 from \$14.8 million for the same period in 2014. The increase included increases of \$1.5 million in salary costs, \$157,000 for recruiting and hiring costs, \$109,000 for administrative expenses and \$90,000 in depreciation and amortization, partially offset by a \$754,000 decrease in legal and professional fees in 2015 compared to 2014. As a percentage of total revenue, general and administrative expenses decreased to 26% for the year ended December 31, 2015 from 30% for the same period in 2014.

Change in fair value of contingent purchase price consideration

The charges of \$202,000 in 2015 and \$72,000 in 2014 related to the change in the fair value of contingent purchase price consideration resulting from the acquisition of Boulder in July 2014.

Intangible assets impairment charges

The charge in 2015 mainly related to the timeline for the development of an assay to inform decisions regarding biologic therapies that was acquired as part of the Boulder acquisition that was changed due to delays in the completion of research studies. Based upon the changed timeline and the resulting impact on fair value, we recorded a non-cash IPR&D impairment charge of \$385,000.

Interest expense, net

Interest expense, net was \$67,000 for the year ended December 31, 2015, compared to \$52,000 in the same period in 2014. Interest expense in both periods primarily related to the fit out of our Marlborough facility.

Foreign exchange losses

We recorded foreign exchange losses of \$143,000 for the year ended December 31, 2015 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, 2014, we recorded foreign exchange losses of \$352,000. We are exposed to foreign exchange rate risk because we currently operate in three major regions of the world: the United States, Europe & ROW and Asia, and our revenue is denominated in multiple currencies. Approximately 50% of our sales were in the United States, which are denominated in U.S. Dollars. Sales in China are 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 & 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 and China.

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 income

Other income was \$54,000 for the year ended December 31, 2015, compared to \$245,000 in the same period in 2014. Other income for 2015 consisted largely of grant income of \$168,000, partially offset by severance expense of \$112,000. Other income in 2014 consisted largely of a \$149,000 U.K. research grant and an \$83,000 Tennessee FastTrack Job Training Assistance program.

Liquidity and capital resources

Sources of funds

Since our inception, we have incurred significant net losses and negative cash flows from operations. For the year ended December 31, 2016 we had a net loss of \$22.3 million and used \$21.9 million of cash for operating activities. As of December 31, 2016, we had an accumulated deficit of \$168.7 million. We incurred a net loss of \$24.5 million and used \$16.5 million of cash for operating activities for the year ended December 31, 2015.

On January 29, 2015, we entered into an underwriting agreement with a group of underwriters relating to the public offering, or the Offering, of 4,255,319 ordinary shares, nominal value £0.006705, or the Shares, at an offering price to the public of \$11.75 per Share, or the Offering Price. The underwriters agreed to purchase the Shares from us pursuant to an underwriting agreement at a price of \$11.045 per share. Under the terms of the underwriting agreement, we granted the underwriters a 30-day option to purchase up to an additional 638,297 shares, or the Option Shares, at the Offering Price, less underwriting discounts and commissions. On January 30, 2015, the underwriters exercised their option to purchase the Option Shares in full. The total proceeds to us from the sale of the Shares and the Option Shares were approximately \$57.5 million and we received net proceeds of approximately \$53.8 million after deducting underwriting discounts and commissions and aggregate offering expenses payable by us. The Offering closed on February 4, 2015.

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On October 4, 2016, we entered into an agreement with MidCap Financial, or the MidCap agreement, that provides us with \$40 million in debt financing, comprised of both a term loan and a revolving line of credit. The MidCap agreement provides us with a term loan of \$30 million, which matures five years from closing. The term loan accrues 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 begins to amortize. The MidCap agreement also provides us with a revolving line of credit of up to \$10 million, which matures five years from closing. The revolving line of credit accrues interest at a rate of LIBOR plus 4.45%. Based on certain conditions, both the term loan and revolving line of credit may be increased by an additional \$10 million for a total of \$60 million.

Additionally, we maintain a shelf registration statement on Form S-3 with the SEC covering our ordinary shares and other securities, and provides us with the opportunity to raise funding when needed or otherwise considered appropriate at prices and on terms to be determined at the time of any such offerings.

As of December 31, 2016, we had cash and cash equivalents of \$59.1 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.

Summary of cash flows

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

(in thousands)	As of and for the years ended December 31,	
	2016	2015
Cash and cash equivalents, excluding restricted cash	\$ 59,110	\$ 83,715
Accounts receivable, net	13,265	7,058
Net cash used in operating activities	\$ (21,921)	\$ (16,549)
Net cash used in investing activities	(30,018)	(3,122)
Net cash provided by financing activities	29,114	53,661
Effect of exchange rate changes on cash and cash equivalents	(1,780)	(440)
Net (decrease) increase in cash and cash equivalents, excluding restricted cash	<u>\$ (24,605)</u>	<u>\$ 33,550</u>

Cash flows for the years ended December 31, 2016 and 2015

Operating activities

Net cash used in operating activities was \$21.9 million during the year ended December 31, 2016, which included a net loss of \$22.3 million and cash used for changes in operating assets less liabilities of \$8.2 million, partially offset by net non-cash items of \$8.7 million. The cash used for changes in operating assets and liabilities included an increase in accounts receivable, net of \$6.5 million, an increase in prepaid expenses and other assets of \$2.9 million, a decrease in deferred income of \$1.7 million, a decrease in accounts payable of \$1.1 million and an increase in inventory, net of \$0.7 million, partially offset by a \$4.8 million increase in accrued liabilities. 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 increase in prepaid expenses and other assets largely reflects the timing of certain payments. 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 decrease in accounts payable was largely due to the timing of payments. The increase in inventory, net was largely due to timing. The increase in accrued liabilities reflects the timing of certain payments. The non-cash items consisted of share-based compensation expense of \$5.0 million, depreciation and amortization expense of \$3.1 million, an intangible assets impairment charge of \$1.8 million mainly related to IPR&D acquired from Boulder and the change in fair value of contingent purchase price consideration of \$244,000. These expenses were partially offset by a \$1.5 million write-off of contingent purchase price consideration, which included \$901,000 from the strategic decision to end our GoutiFind program and \$551,000 from the determination that an assay for Lyme disease that was acquired in conjunction with the Boulder acquisition would not qualify for future milestone payments.

Net cash used in operating activities was \$16.5 million during the year ended December 31, 2015, which included a net loss of \$24.5 million, non-cash items of \$6.3 million and cash provided by changes in operating assets less liabilities of \$1.6 million. The non-cash items consisted of share-based compensation expense of \$3.5 million, depreciation and amortization expense of \$2.1 million, intangible assets impairment charges of \$419,000, consisting largely of an IPR&D impairment charge of \$385,000 related to the Boulder acquisition, a \$202,000 expense from the change in fair value of contingent purchase price consideration and a \$33,000 loss on disposal of property and equipment. The cash provided by changes in operating assets and liabilities included an increase in accounts payable and accrued liabilities of \$4.1 million, partially offset by increases in prepaid expenses and other assets, inventory and accounts receivable, net of \$898,000, \$893,000 and \$416,000, respectively, as well as a decrease in deferred income of \$250,000. The increase in accounts payable and accrued liabilities was largely due to the timing of payments. The increase in prepaid expenses and other assets reflected the timing of certain payments and inventory increased in anticipation of growing revenue. The increase in accounts receivable, net primarily reflected increased revenue during the year ended December 31, 2015, as well as the timing of receipts. 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 resulted in those sales being recorded upon shipment.

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Investing activities

Net cash used in investing activities was \$30.0 million and \$3.1 million for the years ended December 31, 2016 and 2015, respectively. The cash used in 2016 consisted largely of a net \$27.5 million used to finance the acquisitions of Imugen and Immunetics and \$2.4 million used for purchases of property and equipment. The cash used in 2015 consisted largely of \$3.4 million used for purchases of property and equipment, partially offset by a \$312,000 decrease in restricted cash.

Financing activities

Net cash provided by financing activities was \$29.1 million during the year ended December 31, 2016, which mainly reflects the \$30.0 million MidCap borrowing, net of related discount and debt issuance costs.

Net cash provided by financing activities was \$53.7 million during the year ended December 31, 2015, due mainly to net proceeds of approximately \$53.8 million received in the offering that closed on February 4, 2015.

Cash flows for the years ended December 31, 2015 and 2014

Operating activities

Net cash used in operating activities was \$16.5 million during the year ended December 31, 2015, which included a net loss of \$24.5 million, non-cash items of \$6.3 million and cash provided by changes in operating assets less liabilities of \$1.6 million. The non-cash items consisted of share-based compensation expense of \$3.5 million, depreciation and amortization expense of \$2.1 million, intangible assets impairment charges of \$419,000, consisting largely of an IPR&D impairment charge of \$385,000 related to the Boulder acquisition, a \$202,000 expense from the change in fair value of contingent purchase price consideration and a \$33,000 loss on disposal of property and equipment. The cash provided by changes in operating assets and liabilities included an increase in accounts payable and accrued liabilities of \$4.1 million, partially offset by increases in prepaid expenses and other assets, inventory and accounts receivable, net of \$898,000, \$893,000 and \$416,000, respectively, as well as a decrease in deferred income of \$250,000. The increase in accounts payable and accrued liabilities was largely due to the timing of payments. The increase in prepaid expenses and other assets reflected the timing of certain payments and inventory increased in anticipation of growing revenue. The increase in accounts receivable, net primarily reflected increased revenue during the year ended December 31, 2015, as well as the timing of receipts. 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 resulted in those sales being recorded upon shipment.

Net cash used in operating activities was \$20.8 million during the year ended December 31, 2014, which included a net loss of \$22.2 million, non-cash items of \$4.3 million, and a net increase in operating assets less liabilities of \$2.9 million. The non-cash items consisted of share-based compensation expense of \$2.5 million, depreciation and amortization expense of \$1.7 million and a \$22,000 loss on the change in fair value of warrants. We had a net cash outflow of \$2.9 million from changes in operating assets and liabilities during the period. The changes in operating assets and liabilities included an increase in accounts receivable of \$2.3 million, an increase in inventory of \$1.2 million and an increase in prepaid expenses and other assets of \$594,000, partially offset by an increase in accounts payable and accrued liabilities of \$587,000, and an increase in deferred income of \$572,000. The increase in accounts receivable primarily reflected increased revenue during the year ended December 31, 2014, as well as the timing of receipts. Inventory increased in anticipation of growing revenue and the increase in prepaid expenses and other assets reflected the timing of certain payments. The increase in accounts payable and accrued liabilities was largely due to the timing of payments. The increase in deferred income related to the growth in sales to our Japanese importer.

Investing activities

Net cash used in investing activities was \$3.1 million and \$5.0 million for the years ended December 31, 2015 and 2014, respectively. The cash used in 2015 consisted largely of \$3.4 million used for purchases of property and equipment, partially offset by a \$312,000 decrease in restricted cash. The cash used in 2014 consisted largely of \$3.0 million used for purchases of property and equipment and \$1.7 million used in the acquisition of Boulder, net of cash acquired.

Financing activities

Net cash provided by financing activities was \$53.7 million during the year ended December 31, 2015 due mainly to net proceeds of approximately \$53.8 million received in the offering that closed on February 4, 2015.

Net cash used in financing activities was \$151,000 during the year ended December 31, 2014.

Operating and capital expenditure requirements

We have not achieved 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 market 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, 2016.

(in thousands)	Payments due by period				
	Total	Less than 1 year	1-3 Years	3-5 Years	More than 5 years
Operating lease obligations	\$ 7,180	\$ 1,945	\$ 3,258	\$ 1,785	\$ 192
License commitments	4,561	1,518	3,018	25	—
Purchase commitments	4,636	4,189	447	—	—
MidCap term loan	30,000	—	11,667	18,333	—
Total	\$ 46,377	\$ 7,652	\$ 18,390	\$ 20,143	\$ 192

In addition to the MidCap term loan payments listed above, we are required to pay an exit fee of 6.0% of the aggregate principal amount of all term loan borrowings (currently equal to \$1.8 million).

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 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

We derive revenue from the sale of our diagnostic tests to a broad range of customers including hospitals, public health departments, commercial testing laboratories, importers and distributors. We offer our T-SPOT.TB test in either an *in vitro* diagnostic kit or a service format. In addition, as a result of our recent acquisitions of Imugen and Immunetics, we offer tick-borne disease tests in both kit and service formats.

Revenue from tests is generally paid directly by the customer and is recognized on the accrual basis when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) the kit has been shipped or delivered or, in the case of tests performed in our laboratory, when final results have been reported to the customer; (3) the price is fixed or determinable; and (4) collectibility is reasonably assured.

In the United States, we also generate revenue from payments that are received from a variety of third-party payors, including government programs (Medicare and Medicaid) and commercial insurance companies, each with different billing requirements. Revenue from tests paid by third-party payors is recognized on an accrual basis based on our historical collection experience.

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Accounts receivable are primarily amounts due from hospitals, public health departments, commercial testing laboratories, distributors and universities in addition to third-party payors such as commercial insurance companies (including managed care organizations), government programs (Medicare and Medicaid in the United States) and individual patients.

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 in relation to amounts billed, channel mix, any specific customer collection issues that have been identified and other relevant information. Our provision for uncollectible accounts is recorded as bad debt expense and included in general and administrative expenses. Although we believe amounts provided are adequate, the ultimate amounts of uncollectible accounts receivable could be in excess of the amounts provided.

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 a tax return in the financial statements. 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, 2016, 2015 or 2014.

Share-based compensation

Share-based compensation relates to grants of options to purchase ordinary shares and restricted shares. Currently, we maintain one share incentive plan pursuant to which we may grant options to purchase our ordinary shares, restricted shares, restricted share units, and other share-based awards to our employees, directors and officers. This incentive plan is called the Oxford Immunotec Global PLC 2013 Share Incentive Plan, or the 2013 Plan. In addition, we maintain the 2008 Amended and Restated Stock Incentive Plan, or the 2008 Plan. No new share grants or awards will be made under the 2008 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 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.

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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 are required 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.

Goodwill and Indefinite-lived Intangible Assets

Goodwill

Goodwill is not amortized but is reviewed for impairment at least annually, 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.

Indefinite-lived Intangible Assets

Our indefinite-lived intangible assets consist of acquired IPR&D related to our business combinations with Boulder, Imugen and Immunetics, which were recorded at fair value on the acquisition date. IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but is 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, we perform 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. 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 our indefinite-lived intangible asset is impaired. If we choose to first assess qualitative factors and it is determined that it is not more likely than not our indefinite-lived intangible asset 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. The determinations as to whether, and, if so, the extent to which, acquired IPR&D 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, our overall business strategy, and regulatory, market and economic environment and trends.

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

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. This guidance will be effective for us for annual and interim periods beginning after December 15, 2017. Early adoption is permitted for annual and interim periods beginning after December 15, 2016. The guidance allows for either “full retrospective” adoption, meaning the standard is applied to all of the periods presented, or “modified retrospective” adoption, meaning the standard is applied only to the most current period presented in the financial statements. The FASB has recently issued several amendments to the standard, including clarification on accounting for licenses of intellectual property, identifying performance obligations and other technical corrections. We currently anticipate adopting ASU 2014-09 in the first quarter of 2018 and currently intend to apply the “modified retrospective” approach. We are still evaluating ASU 2014-09 and have not yet determined how it may impact our financial position, results of operations or related disclosures.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern*, or ASU 2014-15. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and all annual and interim periods thereafter. Early application is permitted. ASU 2014-15 requires that management evaluate at each annual and interim reporting period whether there is a substantial doubt about an entity’s ability to continue as a going concern within one year of the date that the financial statements are issued. We adopted ASU 2014-15 on October 1, 2016 and there was no impact on our financial position, results of operations or related disclosures.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*, or ASU 2015-11. ASU 2015-11 requires that an entity should measure inventory within the scope of ASU 2015-11 at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. This guidance will be effective for us for annual and interim periods beginning after December 15, 2016. The amendments in ASU 2015-11 are to be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. We are currently evaluating ASU 2015-11 but do not anticipate that adoption of this guidance will have a material impact on our financial position, results of operations or related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases*, or ASU 2016-02. ASU 2016-02 requires lessees to put most leases on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting. The guidance also eliminates real estate-specific provisions for all entities. The new guidance will be effective for us for annual and interim periods beginning after December 15, 2018. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted. We are currently evaluating ASU 2016-02 and have not yet determined how it may impact our financial position, results of operations or related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. ASU 2016-09 is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification on the statement of cash flows and forfeitures. The new guidance will be effective for us for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. The guidance can be applied using a modified retrospective, retrospective, or prospective transition method, depending on a specific amendment. We do not expect the adoption of ASU 2016-09 to have a material impact on our financial position, results of operations or related disclosures.

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 us 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. We are currently evaluating ASU 2016-13 and have not yet determined how it may impact our financial position, results of operations or related disclosures.

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 new guidance will be effective for us for annual and interim periods beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The guidance should be applied retrospectively. We are currently evaluating ASU 2016-15 and have not yet determined how it may impact our statement of cash flows.

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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 guidance is effective for annual periods beginning after December 15, 2017, and early adoption is permitted as of the beginning of an annual reporting period. ASU 2016-16 amendments should be applied on a modified retrospective basis. We are currently evaluating the impact of the adoption of ASU 2016-16 on our financial position, results of operations or related disclosures.

In November 2016, the FASB issued ASU 2016-18, *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 guidance should be applied retrospectively and is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. We do not expect the adoption of ASU 2016-18 to have a material effect on our 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 new guidance will be effective for us for annual periods beginning after December 15, 2017, including interim periods within those periods. The guidance should be applied on a prospective basis and early adoption is not permitted. We are currently evaluating the impact of adoption of ASU 2017-01 on our financial position, results of operations or related 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 us for annual or any interim goodwill impairment tests in fiscal years beginning after December 15, 2019. We are currently evaluating ASU 2017-04 and have not yet determined how it may impact our financial position, results of operations or related disclosures.

Under the U.S. Jumpstart our Business Startups Act, or the JOBS Act, emerging growth companies that become public can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we are subject to the same new or revised accounting standards as public companies that are not emerging growth companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As of December 31, 2016, we had cash and cash equivalents of \$59.1 million, and restricted cash of \$200,000 pledged as collateral for procurement cards issued by a U.S. commercial bank.

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 and interest expense. Based on our cash and cash equivalents at December 31, 2016, if interest rates went either up or down one percentage point, this could change our interest income by approximately \$0.6 million per annum.

We are also exposed to market risk related to fluctuations in interest rates indexed to LIBOR, which determines the variable interest payments made on our loan payable. However, we do not believe we are subject to any material market risk exposure related to this obligation.

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 & ROW, and Asia, and our revenue is denominated in multiple currencies. Approximately 58% of our sales were in the United States, which are denominated in U.S. Dollars. Sales in China are 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 & 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 and China.

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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 loss per common share is calculated independently for each of the periods presented. Therefore, the sum of the quarterly net 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.

(in thousands, except share and per share data) (unaudited)	Three months ended			
	March 31, 2016	June 30, 2016	September 30, 2016	December 31, 2016
Revenue:				
Product	\$ 8,138	\$ 9,293	\$ 9,713	\$ 9,286
Service	8,972	9,861	16,396	14,419
Total revenue	<u>\$ 17,110</u>	<u>\$ 19,154</u>	<u>\$ 26,109</u>	<u>\$ 23,705</u>
Gross profit	<u>\$ 8,945</u>	<u>\$ 10,548</u>	<u>\$ 14,606</u>	<u>\$ 12,507</u>
Net loss (1)	<u>\$ (7,049)</u>	<u>\$ (6,446)</u>	<u>\$ (3,996)</u>	<u>\$ (4,858)</u>
Net loss per ordinary share—basic and diluted	<u>\$ (0.32)</u>	<u>\$ (0.29)</u>	<u>\$ (0.18)</u>	<u>\$ (0.22)</u>
Weighted-average shares used to compute net loss per ordinary share—basic and diluted	<u>22,284,392</u>	<u>22,351,645</u>	<u>22,365,349</u>	<u>22,412,691</u>

(1) The three months ended December 31, 2016 includes impairment charges of \$1.8 million, which included a \$1.5 million impairment charge for Boulder IPR&D and a \$306,000 fixed asset impairment charge, partially offset by a \$1.2 million benefit due to the change in fair value of contingent consideration.

(in thousands, except share and per share data) (unaudited)	Three months ended			
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015
Revenue:				
Product	\$ 7,122	\$ 6,613	\$ 8,310	\$ 8,162
Service	6,679	7,639	9,634	8,623
Total revenue	<u>\$ 13,801</u>	<u>\$ 14,252</u>	<u>\$ 17,944</u>	<u>\$ 16,785</u>
Gross profit	<u>\$ 7,146</u>	<u>\$ 7,750</u>	<u>\$ 9,875</u>	<u>\$ 8,467</u>
Net loss	<u>\$ (6,311)</u>	<u>\$ (7,294)</u>	<u>\$ (4,483)</u>	<u>\$ (6,390)</u>
Net loss per ordinary share—basic and diluted	<u>\$ (0.31)</u>	<u>\$ (0.33)</u>	<u>\$ (0.20)</u>	<u>\$ (0.29)</u>
Weighted-average shares used to compute net loss per ordinary share—basic and diluted	<u>20,331,411</u>	<u>22,245,682</u>	<u>22,259,840</u>	<u>22,264,307</u>

Our revenue fluctuates from quarter to quarter as a result of a number of factors, many of which are outside our control. Our service revenue has historically been strong in the third quarter as a result of a concentration of testing in the United States related to college students returning to school, while the fourth quarter has historically been weaker due to the holiday periods and decreased screening activity in hospitals as they focus on other priorities. 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 seasonality and quarter-to-quarter variations in our revenue.

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 effective to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Chief Executive and Chief Financial Officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

(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). Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on the framework in *Internal Control—Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission. Based on our evaluation under the framework, our management concluded that our internal control over financial reporting was effective as of December 31, 2016.

(c) Changes in internal control over financial reporting

On July 1, 2016, we acquired substantially all of the assets of Imugen and on October 12, 2016, we acquired Immunetics. Prior to these acquisitions, Imugen and Immunetics each operated under their own sets of systems and internal controls. During the fourth quarter of 2016, we transitioned certain of Imugen's and Immunetics' processes to our internal control processes and we expect to transition more of such processes during fiscal 2017.

Other than with respect to our transitions of the acquired businesses to our systems and control environment as described above, 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 2016 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other information

None.

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, 2016.

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, 2016.

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, 2016.

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, 2016.

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, 2016.

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 1, 2016, 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+	License and Supply Agreement dated December 22, 2009 between Statens Serum Institut and Oxford Immunotec Limited (Filed as Exhibit 10.4 of Amendment No. 1 of our Registration Statement on Form S-1 (File No. 333-191737) on October 25, 2013 and incorporated herein by reference.)
10.2	Supplement dated November 9, 2010 to License and Supply Agreement between Statens Serum Institut and Oxford Immunotec Limited (Filed as Exhibit 10.5 of Amendment No. 1 of our Registration Statement on Form S-1 (File No. 333-191737) on October 25, 2013 and incorporated herein by reference.)
10.3+	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.)
10.4	Amendment to Supply Agreement dated April 5, 2016 between MicroCoat Biotechnologie GmbH and Oxford Immunotec Limited (Filed as Exhibit 10.2 to our Current Report on Form 8-K on May 4, 2016, and incorporated herein by reference.)
10.5+	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.)
10.6+	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.)
10.7+	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.)

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Exhibit number	Description of exhibit
10.8	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.)
10.9	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.)
10.10 ⁺	Supply Agreement dated January 1, 2009 between EMD Millipore Corporation and Oxford Immunotec Ltd (Filed as Exhibit 10.17 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.11 ⁺	First Amendment to Supply Agreement dated September 27, 2013 between EMD Millipore Corporation and Oxford Immunotec Limited (Filed as Exhibit 10.18 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.12 ⁺	Second Amendment to Supply Agreement dated March 25, 2014 between EMD Millipore Corporation and Oxford Immunotec Limited (Filed as Exhibit 10.20 of our Form 10-K on March 27, 2014 and incorporated herein by reference.)
10.13 ⁺	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.)
10.14 ⁺	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.)
10.15 ⁺	Supply and Reseller Agreement dated August 12, 2013 between Life Technologies Corporation and Oxford Immunotec Limited (Filed as Exhibit 10.21 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.16 ⁺	First Amendment to Supply and Reseller Agreement ,dated April 1, 2014 between Life Technologies Corporation and Oxford Immunotec Limited (Filed as Exhibit 10.1 of our Form 8-K on April 3, 2014 and incorporated herein by reference.)
10.17 ⁺	Second Amendment to Supply and Reseller Agreement ,dated August 9, 2016 between Life Technologies Corporation and Oxford Immunotec Limited (Filed as Exhibit 10.1 of our Form 10-Q on November 1, 2016 and incorporated herein by reference.)
10.18 ⁺	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.)
10.19 ⁺	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.)
10.20 ⁺	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.
10.21 ⁺	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.)
10.22 ⁺	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.)
10.23	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 Current Report on Form 8-K on May 4, 2016, and incorporated herein by reference.)
10.24	Credit, Security and Guaranty Agreement (Term Loan), dated October 4, 2016, among Oxford Immunotec Global PLC, Oxford Immunotec, Inc., Oxford Immunotec Limited, the lenders from time to time party thereto and MidCap Financial Trust, individually as a lender and as administrative agent (Filed as Exhibit 10.1 of our Form 8-K on October 7, 2016 and incorporated herein by reference.)

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Exhibit number	Description of exhibit
10.25	Credit, Security and Guaranty Agreement (Revolving Loan), dated October 4, 2016, among Oxford Immunotec Global PLC, Oxford Immunotec, Inc., Oxford Immunotec Limited, the lenders from time to time party thereto and MidCap Financial Trust, individually as a lender and as administrative agent (Filed as Exhibit 10.2 of our Form 8-K on October 7, 2016 and incorporated herein by reference.)
10.26	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.)
10.27	Form of Incentive Stock Option Award for executive officers under the Amended and Restated 2008 Stock Incentive Plan (Filed as Exhibit 10.36 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.28	Form of Non-Statutory Stock Option Award for Non-Executive Directors under the Amended and Restated 2008 Stock Incentive Plan (Filed as Exhibit 10.37 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.29	Form of Enterprise Management Incentive Stock Option Agreement for Chief Executive Officer under the Amended and Restated 2008 Stock Incentive Plan (Filed as Exhibit 10.38 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.30	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.)
10.31	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.)
10.32	Form of First Amendment to Officer Restricted Share Award 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.)
10.33	Form of Amendment to the Restricted Share Award (Revised Vesting) under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.36 of our Form 10-K on March 1, 2016 and incorporated herein by reference.)
10.34	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.)
10.35	Form of CSOP award certificate under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.3 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.36	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 Form 10-K on March 1, 2016 and incorporated herein by reference.)
10.37	Form of unapproved option under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United Kingdom (Filed as Exhibit 10.4 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.38	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.)
10.39	Form of stock option agreement under the Oxford Immunotec Global PLC 2013 Share Incentive Plan for officers resident in the United States (Filed as Exhibit 10.5 of our Form 8-K on March 6, 2014 and incorporated herein by reference.)
10.40	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 Form 10-K on March 1, 2016 and incorporated herein by reference.)
10.41	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 Form 10-K on March 1, 2016 and incorporated herein by reference.)
10.42	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 Form 10-K on March 27, 2014 and incorporated herein by reference.)

Exhibit number	Description of exhibit
10.43	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.)
10.44	Amended and Restated Employment Agreement dated October 1, 2013 between Oxford Immunotec, Inc. and Jeff R. Schroeder (Filed as Exhibit 10.42 of our Registration Statement on Form S-1 (File No. 333-191737) on October 15, 2013 and incorporated herein by reference.)
10.45	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.)
10.46	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.)
10.47	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.)
10.48	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.)
10.49	Form of Director Stock Option Award under Oxford Immunotec Global PLC 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.)
10.50	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.)
21.1	List of Subsidiaries
23.1	Consent of Ernst & Young LLP
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, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated balance sheets as of December 31, 2016 and 2015; (ii) Consolidated statements of operations for the years ended December 31, 2016, 2015 and 2014; (iii) Consolidated statements of other comprehensive loss for the years ended December 31, 2016, 2015 and 2014; (iv) Consolidated statements of shareholders' equity for the years ended December 31, 2016, 2015 and 2014; (v) Consolidated statements of cash flows for the years ended December 31, 2016, 2015 and 2014; 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 Securities and Exchange Commission.

Item 16. Form 10-K Summary

None.

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 February 28, 2017.

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 February 28, 2017 in the capacities indicated below.

Signature	Title	Date
<u>/s/ Peter Wrighton-Smith, Ph.D.</u> Peter Wrighton-Smith, Ph.D.	Chief Executive Officer and Director (Principal Executive Officer)	February 28, 2017
<u>/s/ Richard M. Altieri</u> Richard M. Altieri	Chief Financial Officer (Principal Financial and Accounting Officer)	February 28, 2017
<u>/s/ Richard A. Sandberg</u> Richard A. Sandberg	Chairman of the Board of Directors	February 28, 2017
<u>/s/ Ronald Andrews Jr.</u> Ronald Andrews Jr.	Director	February 28, 2017
<u>/s/ Patrick J. Balthrop, Sr.</u> Patrick J. Balthrop, Sr.	Director	February 28, 2017
<u>/s/ Patricia Randall</u> Patricia Randall	Director	February 28, 2017
<u>/s/ Herm Rosenman</u> Herm Rosenman	Director	February 28, 2017
<u>/s/ Stephen L. Spotts</u> Stephen L. Spotts	Director	February 28, 2017
<u>/s/ James R. Tobin</u> James R. Tobin	Director	February 28, 2017
<u>/s/ A. Scott Walton</u> A. Scott Walton	Director	February 28, 2017
<u>/s/ Richard M. Altieri</u> Richard M. Altieri	Authorized Representative in the United States	February 28, 2017

Oxford Immunotec Global PLC

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Audited consolidated financial statements

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Report of independent registered public accounting firm

The Board of Directors and Shareholders of Oxford Immunotec Global PLC:

We have audited the accompanying consolidated balance sheets of Oxford Immunotec Global PLC as of December 31, 2016 and 2015, and the related consolidated statements of operations, other comprehensive loss, shareholders' equity, and cash flows for each of the three years in the period ended December 31, 2016. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Oxford Immunotec Global PLC at December 31, 2016 and 2015, and the consolidated results of its operations and its cash flows for each of the three years in the period ended December 31, 2016, in conformity with U.S. generally accepted accounting principles.

/s/ Ernst & Young LLP

Reading, United Kingdom

February 28, 2017

Oxford Immunotec Global PLC

Consolidated balance sheets

(in thousands, except share and per share data)

	December 31,	
	2016	2015
Assets		
Current assets:		
Cash and cash equivalents	\$ 59,110	\$ 83,715
Accounts receivable, net	13,265	7,058
Inventory, net	7,437	7,099
Prepaid expenses and other	2,390	3,592
Total current assets	82,202	101,464
Restricted cash, non-current	200	80
Property and equipment, net	7,793	6,284
In-process research and development	16,170	1,782
Goodwill	3,822	45
Other intangible assets, net	11,017	179
Other assets	2,808	18
Total assets	<u>\$ 124,012</u>	<u>\$ 109,852</u>
Liabilities and shareholders' equity		
Current liabilities:		
Accounts payable	\$ 3,201	\$ 3,799
Accrued liabilities	14,282	9,949
Contingent purchase price consideration	882	—
Deferred income	41	1,654
Current portion of loans payable	84	79
Total current liabilities	18,490	15,481
Long-term portion of loans payable	29,601	386
Contingent purchase price consideration	2,593	1,293
Other liabilities	364	—
Total liabilities	<u>51,048</u>	<u>17,160</u>
Commitments and contingencies (Note 15)		
Shareholders' equity:		
Ordinary shares, £0.006705 nominal value; 36,183,293 shares authorized at December 31, 2016 and 2015, 22,635,431 and 22,549,488 shares issued and outstanding at December 31, 2016 and 2015, respectively	243	243
Additional paid-in capital	249,128	244,033
Accumulated deficit	(168,656)	(146,307)
Accumulated other comprehensive loss	(7,751)	(5,277)
Total shareholders' equity	<u>72,964</u>	<u>92,692</u>
Total liabilities and shareholders' equity	<u>\$ 124,012</u>	<u>\$ 109,852</u>

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of operations
(in thousands, except share and per share data)

	Year ended December 31,		
	2016	2015	2014
Revenue			
Product	\$ 36,430	\$ 30,207	\$ 25,407
Service	49,648	32,575	24,098
Total revenue	<u>86,078</u>	<u>62,782</u>	<u>49,505</u>
Cost of revenue			
Product	13,956	13,297	11,225
Service	25,516	16,247	12,784
Total cost of revenue	<u>39,472</u>	<u>29,544</u>	<u>24,009</u>
Gross profit	46,606	33,238	25,496
Operating expenses:			
Research and development	13,881	10,381	6,961
Sales and marketing	34,964	30,402	25,487
General and administrative	23,181	16,010	14,837
Change in fair value of contingent purchase price consideration	(1,208)	202	72
Intangible assets impairment charges	1,765	419	—
Total operating expenses	<u>72,583</u>	<u>57,414</u>	<u>47,357</u>
Loss from operations	(25,977)	(24,176)	(21,861)
Other income (expense):			
Interest expense, net	(864)	(67)	(52)
Foreign exchange gains (losses)	1,364	(143)	(352)
Other (expense) income	(646)	54	245
Loss before income taxes	(26,123)	(24,332)	(22,020)
Income tax benefit (expense)	3,774	(146)	(154)
Net loss	<u>\$ (22,349)</u>	<u>\$ (24,478)</u>	<u>\$ (22,174)</u>
Net loss per ordinary share—basic and diluted	<u>\$ (1.00)</u>	<u>\$ (1.12)</u>	<u>\$ (1.28)</u>
Weighted-average shares used to compute net loss per ordinary share—basic and diluted	<u>22,353,713</u>	<u>21,781,933</u>	<u>17,310,148</u>

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of other comprehensive loss
(in thousands)

	Year ended December 31,		
	2016	2015	2014
Net loss	\$ (22,349)	\$ (24,478)	\$ (22,174)
Other comprehensive loss, net of taxes:			
Foreign currency translation adjustment, net of taxes	(2,474)	(707)	(822)
Other comprehensive loss, net of taxes	(2,474)	(707)	(822)
Total comprehensive loss	<u>\$ (24,823)</u>	<u>\$ (25,185)</u>	<u>\$ (22,996)</u>

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of shareholders' equity
(in thousands)

	Ordinary shares	Additional paid-in capital	Accumulated deficit	Accumulated other comprehensive loss	Total shareholders' equity
Balance at December 31, 2013	\$ 188	\$ 183,967	\$ (99,655)	\$ (3,748)	\$ 80,752
Exercise of share options	1	13	—	—	14
Issuance of shares from option plan	3	(3)	—	—	—
Issuance of shares from exercise of warrants	—	318	—	—	318
Share-based compensation expense	—	2,521	—	—	2,521
Other comprehensive loss	—	—	—	(822)	(822)
Net loss	—	—	(22,174)	—	(22,174)
Balance at December 31, 2014	192	186,816	(121,829)	(4,570)	60,609
Exercise of share options	1	19	—	—	20
Issuance of shares in secondary offering	50	53,713	—	—	53,763
Share-based compensation expense	—	3,485	—	—	3,485
Other comprehensive loss	—	—	—	(707)	(707)
Net loss	—	—	(24,478)	—	(24,478)
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

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of cash flows
(in thousands)

	Year ended December 31,		
	2016	2015	2014
Cash flows from operating activities			
Net loss	\$ (22,349)	\$ (24,478)	\$ (22,174)
Adjustments to reconcile net loss to net cash used in operating activities:			
Depreciation and amortization of intangible assets and loan fees	3,094	2,142	1,742
Change in fair value of contingent purchase price consideration	244	202	72
Write-off of contingent purchase price consideration	(1,452)	—	—
Intangible assets impairment charges	1,765	419	—
Share-based compensation expense	5,019	3,485	2,521
Loss on change in fair value of warrants	—	—	22
Loss on disposal of property and equipment	—	33	—
Changes in operating assets and liabilities:			
Accounts receivable, net	(6,515)	(416)	(2,311)
Inventory, net	(741)	(893)	(1,214)
Prepaid expenses and other assets	(2,926)	(898)	(594)
Accounts payable	(1,145)	1,363	(109)
Accrued liabilities	4,753	2,742	696
Deferred income	(1,668)	(250)	572
Net cash used in operating activities	<u>(21,921)</u>	<u>(16,549)</u>	<u>(20,777)</u>
Cash flows from investing activities			
Purchases of property and equipment	(2,383)	(3,425)	(3,014)
Purchases of intangible assets	—	(43)	(354)
Cash paid for acquisitions, net of cash acquired	(27,515)	—	(1,716)
Proceeds on sales of property and equipment	—	34	—
Change in restricted cash	(120)	312	57
Net cash used in investing activities	<u>(30,018)</u>	<u>(3,122)</u>	<u>(5,027)</u>
Cash flows from financing activities			
Proceeds from issuance of ordinary shares	—	53,763	—
Proceeds from exercise of share options	76	20	14
Proceeds from term loan, net	29,457	—	—
Discount on the line of credit	(50)	—	—
Debt issuance costs	(289)	—	—
Payments on loan	(80)	(122)	(165)
Net cash provided by (used in) financing activities	<u>29,114</u>	<u>53,661</u>	<u>(151)</u>
Effect of exchange rate changes on cash and cash equivalents	<u>(1,780)</u>	<u>(440)</u>	<u>(374)</u>
Net (decrease) increase in cash and cash equivalents, excluding restricted cash	(24,605)	33,550	(26,329)
Cash and cash equivalents at beginning of year	83,715	50,165	76,494
Cash and cash equivalents at end of year	<u>\$ 59,110</u>	<u>\$ 83,715</u>	<u>\$ 50,165</u>

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC
Consolidated statements of cash flows (continued)
(in thousands)

	Year ended December 31,		
	2016	2015	2014
Supplemental disclosures			
Cash paid for interest	\$ 450	\$ 41	\$ 50
Cash paid for taxes	141	50	115
Noncash investing and financing activities			
Warrants liability reclassified to additional paid-in capital upon exercise of warrants	\$ —	\$ —	\$ 318

See accompanying notes to these consolidated financial statements.

Oxford Immunotec Global PLC

Notes to consolidated financial statements

1. Description of business and significant accounting policies

Description of business

Oxford Immunotec Global PLC, or the Company, is a global, high-growth diagnostics company focused on developing and commercializing proprietary tests for under-served immune-regulated conditions. The Company's current product lines and development activities principally focus on four areas: infectious diseases, transplantation, autoimmune and inflammatory disease and immune-oncology. The Company believes these areas are particularly 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. These immune-regulated conditions also tend to be characterized by wide variation in presentation and progression and often require expensive therapies, making diagnostic tests that can better categorize patients and inform treatment pathways particularly useful. Lastly, the Company believes these conditions to be under-served as the industry lacks the appropriate techniques to prosecute the immune responses which are driving these conditions.

On July 1, 2016, the Company acquired substantially all of the assets of Imugen, Inc., or Imugen, a privately owned Massachusetts corporation specializing in the development and performance of testing for tick-borne diseases, including Lyme disease. Using proprietary technology, the Company's tests for tick-borne diseases inform the diagnosis, prognosis and monitoring of tick-borne diseases, which if left untreated can become chronic infections.

On October 12, 2016, the Company acquired Immunetics, Inc., or Immunetics, a privately owned Massachusetts corporation focused on developing specialized tests for infectious diseases, including tick-borne diseases, such as Lyme disease. Total consideration consisted of \$6 million in cash and up to an additional \$6 million in cash payable on the achievement of certain revenue thresholds and pipeline related milestones over the next three years.

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 combined 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 Inc. and Immunetics, Inc., 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 translation gains or losses in accumulated other comprehensive income, which is a component of shareholders' equity. The Company does not record tax provisions or benefits for the net changes in foreign currency translation adjustments, as the Company intends to permanently reinvest undistributed earnings in its foreign subsidiaries.

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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.

Concentration of risks

In the year ended December 31, 2016, 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 15% of annual revenue and the Company's Japanese importer, Riken Genesis Co., Ltd. represented 14% 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 primarily invested in U.S. government securities, and bank savings accounts in the United States, United Kingdom, Germany, Japan and Hong Kong. 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.

Accounts receivable

Accounts receivable are primarily amounts due from customers including hospitals, public health departments, commercial testing laboratories, distributors and universities in addition to third-party payors such as commercial insurance companies and government programs (Medicare and Medicaid).

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 finished goods and raw materials. 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 market. Cost is determined by the actual cost of components by batch plus estimated labor and overhead costs per unit. Market value is based on an estimated selling price less any costs expected to be incurred to completion and sale. The Company reviews the components of its inventory on a periodic basis for excess, obsolete or impaired inventory, and records a reserve for the identified items.

Property and equipment

Property and equipment are stated at cost. Property and equipment includes specialized shipping containers provided to customers, in the United States, for transporting samples to the Company's laboratory for testing. 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 and specialized shipping containers.

Revenue recognition

The Company derives product revenue from the sale of its diagnostic test kits and related accessories to a broad range of customers including hospitals, public health departments, commercial testing laboratories, importers and distributors.

Product revenue is generally paid directly by the customer and is recognized on an accrual basis when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) the product has been shipped or delivered in accordance with the shipping terms of the arrangement; (3) the price is fixed or determinable and known at time of shipment; and (4) collectibility is reasonably assured.

No product return rights are extended to customers of the Company.

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The Company derives service revenue from tests performed on samples sent by customers to its diagnostic laboratories in the United States and the United Kingdom, and to contracted laboratories in other countries.

Service revenue in the United Kingdom and revenue from direct bill customers in the United States are recognized on an accrual basis when the following revenue recognition criteria are met: (1) persuasive evidence that an arrangement exists; (2) when the diagnostic result has been delivered; (3) the price is fixed or determinable; and (4) collectibility is reasonably assured. This service revenue is referred to as “direct-bill” sales because the Company receives payment directly from the ordering entity.

In the United States, the Company also generates revenue from payments that are received from a variety of third-party payors, including government programs (Medicare and Medicaid) and commercial insurance companies, each with different billing requirements. Revenue from tests paid by third-party payors is generally recognized on an accrual basis based on the Company’s historical collection experience. In certain instances, revenue is recognized on a cash basis when there is insufficient historical collection experience.

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, the U.S. medical device excise tax and packaging and delivery costs.

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

Shipping and handling

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

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.

Impairment of long-lived assets

The Company evaluates its long-lived assets 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 is recoverable by comparing the future undiscounted cash flows estimated to be associated with the asset to the asset’s 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. 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, 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 change 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, 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 it is determined that it is not more likely than not goodwill is impaired, it is not required to take further action 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.

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Indefinite-lived intangible assets

The Company's indefinite-lived intangible assets consist of acquired in-process research and development, or IPR&D, related to the Company's business combinations with Boulder, Imugen and Immunetics, which were recorded at fair value on the acquisition dates. IPR&D intangible assets are considered indefinite-lived intangible assets until completion or abandonment of the associated research and development efforts. IPR&D is not amortized but is 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 it is determined that it is not more likely than not its indefinite-lived intangible asset is impaired, it is not required to take further action 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, acquired IPR&D 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. On an ongoing basis, the Company assesses the recoverability of its intangible assets by determining its ability to generate undiscounted future cash flows sufficient to recover the unamortized balances over the remaining useful lives. Intangible assets determined to be unrecoverable are expensed in the period in which the determination is made.

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, 2016 and 2015, 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 2 "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 T-SPOT technology platform and potential future products including new diagnostic tests that utilize the T-SPOT technology platform and are charged to expense as incurred. In addition, with the acquisition of Boulder in 2014 and the acquisitions of Imugen and Immunetics in 2016, the Company has expanded its research efforts to include assays for tick-borne diseases. 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 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. The Company does not have any accrued interest or penalties associated with any unrecognized tax positions for the years ended December 31, 2016 and 2015.

Basic and diluted net loss per ordinary share

Basic and diluted net loss per ordinary share is determined by dividing net loss by the weighted-average number of ordinary shares outstanding during the period. As the Company reports net losses, outstanding share options, RSUs and restricted shares have not been included in the calculation of diluted net loss per share because to do so would be anti-dilutive. Accordingly, the numerator and the denominator used in computing both basic and diluted net loss per ordinary share for each period are the same.

Recent 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. This guidance will be effective for the Company for annual and interim periods beginning after December 15, 2017. Early adoption is permitted for annual and interim periods beginning after December 15, 2016. The guidance allows for either "full retrospective" adoption, meaning the standard is applied to all of the periods presented, or "modified retrospective" adoption, meaning the standard is applied only to the most current period presented in the financial statements. The FASB has recently issued several amendments to the standard, including clarification on accounting for licenses of intellectual property, identifying performance obligations and other technical corrections. The Company currently anticipates adopting ASU 2014-09 in the first quarter of 2018 and currently intends to apply the "modified retrospective" approach. The Company is still evaluating ASU 2014-09 and has not yet determined how it may impact its financial position, results of operations or related disclosures.

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In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements - Going Concern*, or ASU 2014-15. ASU 2014-15 is effective for annual periods ending after December 15, 2016 and all annual and interim periods thereafter. Early application is permitted. ASU 2014-15 requires that management evaluate at each annual and interim reporting period whether there is a substantial doubt about an entity's ability to continue as a going concern within one year of the date that the financial statements are issued. The Company adopted ASU 2014-15 on October 1, 2016 and there was no impact on its financial position, results of operations or related disclosures.

In July 2015, the FASB issued ASU 2015-11, *Simplifying the Measurement of Inventory*, or ASU 2015-11. ASU 2015-11 requires that an entity should measure inventory within the scope of ASU 2015-11 at the lower of cost and net realizable value. Net realizable value is the estimated selling prices in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. This guidance will be effective for the Company for annual and interim periods beginning after December 15, 2016. The amendments in ASU 2015-11 are to be applied prospectively with earlier application permitted as of the beginning of an interim or annual reporting period. The Company is currently evaluating ASU 2015-11 but does not anticipate that adoption of this guidance will have a material impact on its financial position, results of operations or related disclosures.

In February 2016, the FASB issued ASU 2016-02, *Leases*, or ASU 2016-02. ASU 2016-02 requires lessees to put most leases on their balance sheets but recognize expenses on their income statements in a manner similar to current accounting. The guidance also eliminates real estate-specific provisions for all entities. The new guidance will be effective for the Company for annual and interim periods beginning after December 15, 2018. In transition, lessees and lessors are required to recognize and measure leases at the beginning of the earliest period presented using a modified retrospective approach. Early adoption is permitted. The Company is currently evaluating ASU 2016-02 and has not yet determined how it may impact its financial position, results of operations or related disclosures.

In March 2016, the FASB issued ASU 2016-09, *Improvements to Employee Share-Based Payment Accounting*, or ASU 2016-09. ASU 2016-09 is intended to simplify several areas of accounting for share-based compensation arrangements, including the income tax impact, classification on the statement of cash flows and forfeitures. The new guidance will be effective for the Company for annual and interim periods beginning after December 15, 2016. Early adoption is permitted. The guidance can be applied using a modified retrospective, retrospective, or prospective transition method, depending on a specific amendment. The Company does not expect the adoption of ASU 2016-09 to have a material impact on financial position, results of operations or related disclosures.

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 is currently evaluating ASU 2016-13 and has not yet determined how it may impact its financial position, results of operations or related disclosures.

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 new guidance will be effective for the Company for annual and interim periods beginning after December 15, 2017. Early adoption is permitted, including adoption in an interim period. The guidance should be applied retrospectively. The Company is currently evaluating ASU 2016-15 and has not yet determined how it may impact its 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 guidance is effective for annual periods beginning after December 15, 2017, and early adoption is permitted as of the beginning of an annual reporting period. ASU 2016-16 amendments should be applied on a modified retrospective basis. The Company is currently evaluating the impact of the adoption of ASU 2016-16 on its financial position, results of operations or related disclosures.

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In November 2016, the FASB issued ASU 2016-18, *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 guidance should be applied retrospectively and is effective for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted, including adoption in an interim period. The Company does not expect the adoption of ASU 2016-18 to have a material effect on its 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 new guidance will be effective for the Company for annual periods beginning after December 15, 2017, including interim periods within those periods. The guidance should be applied on a prospective basis and early adoption is not permitted. The Company is currently evaluating the impact of adoption of ASU 2017-01 on its financial position, results of operations or related 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. The Company is currently evaluating ASU 2017-04 and has not yet determined how it may impact its financial position, results of operations or related disclosures.

Under the U.S. Jumpstart our Business Startups Act, or the JOBS Act, emerging growth companies that become public can delay adopting new or revised accounting standards until such time as those standards apply to private companies. The Company irrevocably elected not to avail itself of this exemption from new or revised accounting standards and, therefore, it is subject to the same new or revised accounting standards as public companies that are not emerging growth companies.

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

Level II—Observable inputs, other than Level I 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 III—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 maturities.

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.

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The following tables present information about the balances of liabilities measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation techniques it utilized to determine such fair value. In general, fair values determined by Level 1 inputs utilize quoted prices (unadjusted) in active markets for identical assets or liabilities. Fair values determined by Level 2 inputs utilize data points that are observable such as quoted prices, interest rates, and yield curves. Fair values determined by Level 3 inputs are unobservable data points for the asset or liability, and include situations where there is little, if any, market activity for the asset or liability. The Company did not have any financial assets measured at fair value on a recurring basis.

(in thousands)	December 31, 2016	Fair value measurements at December 31, 2016 using		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Liabilities:				
Contingent purchase price consideration	\$ 3,475	\$ —	\$ —	\$ 3,475
Total	<u>\$ 3,475</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,475</u>

(in thousands)	December 31, 2015	Fair value measurements at December 31, 2015 using		
		Quoted prices in active markets for identical assets (Level 1)	Significant other observable inputs (Level 2)	Significant unobservable inputs (Level 3)
Liabilities:				
Contingent purchase price consideration	\$ 1,293	\$ —	\$ —	\$ 1,293
Total	<u>\$ 1,293</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 1,293</u>

The following tables provide a summary of changes in the fair value of the Company's Level 3 financial liabilities for the years ended December 31:

(in thousands)	2016
Balance – beginning	\$ 1,293
Immunetics acquisition (Note 17)	3,444
Change in fair value of contingent purchase price consideration	244
Write-off of Boulder contingent purchase price consideration	(1,452)
Foreign currency adjustment	(54)
Balance – ending	<u>\$ 3,475</u>

(in thousands)	2015
Balance – beginning	\$ 1,218
Change in fair value of contingent purchase price consideration	202
Foreign currency adjustment	(127)
Balance – ending	<u>\$ 1,293</u>

During the fourth quarter of 2016, the decision was made to halt research on the GoutiFind test, which was an assay intended to allow early diagnosis of gout and to better inform therapies by measuring the strength of the underlying uric acid induced inflammation. Based on this decision, the Company wrote off the related contingent purchase price consideration of \$901,000. During the same quarter, the Company determined that the SpiroFind assay developed using IPR&D from Boulder would not qualify for future milestone payments. Due to this fact, the Company wrote off the related contingent purchase price consideration of \$551,000. Both charges have been included in the line “Change in fair value of contingent purchase price consideration” in the consolidated statements of operations. Similar charges recorded in prior years have been reclassified out of research and development expense for comparative purposes.

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On October 12, 2016, the Company acquired Immunetics, a Massachusetts based diagnostics company focused on developing specialized tests for infectious diseases, including tick-borne diseases, such as Lyme disease. The terms of the purchase agreement included contingent purchase price consideration consisting of up to an additional \$6.0 million in cash payable on the achievement of certain revenue thresholds and pipeline related milestones over the next three years. The fair value of these milestone payments has 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%, which are considered as Level 3 inputs.

The Company has a term loan outstanding under the MidCap agreement. The amount outstanding on its 2016 term loan is reported at its carrying value in the accompanying balance sheet. The estimated fair value of the term loan as of December 31, 2016, based upon current market rates for similar borrowings, as measured using Level 2 inputs, approximates the carrying amount as presented on the consolidated balance sheet.

3. Accounts receivable, net

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

(in thousands)	December 31,	
	2016	2015
Accounts receivable	\$ 14,050	\$ 7,372
Less allowance for uncollectible accounts receivable	(785)	(314)
Accounts receivable, net	<u>\$ 13,265</u>	<u>\$ 7,058</u>

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

(in thousands)	December 31,		
	2016	2015	2014
Balance at beginning of period	\$ (314)	\$ (114)	\$ (165)
Provision for bad debt expense	(471)	(200)	—
Write-off, net of recoveries	—	—	51
Balance at end of period	<u>\$ (785)</u>	<u>\$ (314)</u>	<u>\$ (114)</u>

4. Inventory, net

Inventory consisted of the following as of:

(in thousands)	December 31,	
	2016	2015
Raw materials	\$ 4,928	\$ 3,925
Finished goods	2,509	3,174
Inventory	<u>\$ 7,437</u>	<u>\$ 7,099</u>

5. Property and equipment, net

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

(in thousands)	December 31,	
	2016	2015
Laboratory equipment	\$ 5,971	\$ 4,865
Leasehold improvements	3,199	2,783
Office equipment, furniture and fixtures	3,364	2,841
Software	1,479	1,172
Specialized shipping containers	2,655	2,177
Construction in progress	848	200
Property and equipment	17,516	14,038
Less accumulated depreciation	(9,723)	(7,754)
Property and equipment, net	\$ 7,793	\$ 6,284

For the years ended December 31, 2016, 2015 and 2014, the Company recorded depreciation expense of \$2.6 million, \$2.0 million, and \$1.7 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, 2016 and 2015, there were no material capital leases, disposals or retirements.

6. Goodwill and intangible assets

The following table sets forth the changes in the carrying amount of goodwill for the years ended December 31, 2015 and 2016 (in thousands):

Balance at December 31, 2014	\$ 50
Foreign currency adjustment	(5)
Balance at December 31, 2015	45
Imugen acquisition (Note 17)	2,645
Immunetics acquisition (Note 17)	1,177
Impairment charge – Boulder goodwill	(43)
Foreign currency adjustment	(2)
Balance at December 31, 2016	\$ 3,822

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Acquired intangible assets consisted of the following as of December 31, 2016 and 2015 (in thousands):

	As of December 31, 2016			
	Amortization period (years)	Gross carrying amount	Accumulated Amortization	Net carrying amount
Imugen in-process research and development	Indefinite	\$ 9,200	\$ —	\$ 9,200
Imugen technology - clinical	15	5,100	170	4,930
Imugen customer relationships	10	2,700	135	2,565
Imugen trademarks / trade names	16	1,900	59	1,841
Immunetics in-process research and development	Indefinite	6,970	—	6,970
Immunetics technology – clinical	15	860	9	851
Immunetics customer relationships	5 - 11	400	11	389
Immunetics trade name	5	290	9	281
Immunetics grants	2	50	4	46
Other	5 - 10	632	518	114
Total		<u>\$ 28,102</u>	<u>\$ 915</u>	<u>\$ 27,187</u>

	As of December 31, 2015			
	Amortization period (years)	Gross carrying amount	Accumulated Amortization	Net carrying amount
Boulder in-process research and development	Indefinite	\$ 1,782	\$ —	\$ 1,782
Other	5 - 10	758	579	179
Total		<u>\$ 2,540</u>	<u>\$ 579</u>	<u>\$ 1,961</u>

The weighted average amortization period of our finite-lived intangible assets is 13 years. Amortization expense for the years ended December 31, 2016, 2015 and 2014 was \$435,000, \$92,000 and \$43,000, respectively. Amortization expense related to acquired intangible assets is estimated at \$1.0 million per year for the years ending 2017 and 2018 and \$0.9 million per year for each of the years ending 2019 through 2021.

The acquired IPR&D assets include \$9.2 million for IPR&D acquired in conjunction with the Imugen acquisition and \$7.0 million for IPR&D acquired in conjunction with the Immunetics acquisition. During the fourth quarter of 2016, we 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.

IPR&D acquired in a business combination is capitalized at fair value and is subject to impairment testing at least annually until the underlying project is completed. Once the project is completed, the carrying value of IPR&D is amortized over the estimated useful life of the asset. Post-acquisition research and development expenses related to the acquired IPR&D are expensed as incurred. For more information on the acquisitions, see Note 17 “Acquisition activity”.

7. Accrued liabilities

Accrued liabilities consist of the following as of:

(in thousands)	December 31,	
	2016	2015
Employee related expenses	\$ 6,592	\$ 4,478
Royalties	4,423	3,498
Clinical trials	1,135	442
Professional services	387	333
Sales and use taxes payable	155	193
Other accrued liabilities	1,590	1,005
Total accrued liabilities	<u>\$ 14,282</u>	<u>\$ 9,949</u>

8. 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, 2016, \$71,000 is included in the balance sheet in current portion of loans payable and \$236,000 is included in long-term portion of loans payable.

On October 4, 2016, the Company entered into an agreement with MidCap Financial, or the MidCap agreement, that provides it with \$40 million in debt financing, comprised of both a term loan and a revolving line of credit. The MidCap agreement provides the Company with a term loan of \$30 million, which matures five years from closing. The term loan accrues 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 begins to amortize. The MidCap agreement also provides the Company with a revolving line of credit of up to \$10 million, which matures five years from closing. The revolving line of credit accrues interest at a rate of LIBOR plus 4.45%. The Company is 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 may be increased by an additional \$10 million for a total of \$60 million.

If the credit facility is terminated prior to the end of the term, the Company will 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 is obligated to make a final payment fee equal to 6% of the aggregate loan amount.

The credit facility is collateralized by a perfected first priority security interest in all existing and after-acquired assets of the Company.

Under the Credit Agreement, the Company is subject to affirmative covenants which are customary for financings of this type, including, but not limited to, the obligations of the Company to: (i) deliver financial statements and other reports to MidCap, (ii) maintain insurance, (iii) maintain good standing, (iv) comply with all laws and material contracts, (v) provide certain other information and notices to MidCap, and (vi) protect the Company's intellectual property.

The Company is also subject to negative covenants customary for financings of this type, including, but not limited to, that without the prior consent of MidCap, the Company may not: (i) incur additional indebtedness, (ii) incur liens on the collateral, (iii) declare, order or set apart any distribution without permission, (iv) enter into a merger or consolidation or certain change of control events, or acquire another company, (v) amend material agreements or organizational documents, or (vi) enter into certain transactions with affiliates, in each case subject to certain exceptions provided for in the MidCap agreement.

The Company is also subject to financial covenants customary to financings of this type, which require the Company to achieve quarterly targets based on trailing 12 months net revenue. As of December 31, 2016, the Company was in compliance with all its covenants.

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The MidCap Agreement provides that events of default include: (i) failure to make payment of principal or interest when required, (ii) failure to perform obligations under the MidCap agreement and related documents, (iii) defaults in other indebtedness and breaches of material agreements of the Company, (iv) voluntary case or other proceeding by the Company seeking liquidation, reorganization or other relief, (v) if the Company ceases to be a publicly-listed and reporting company and (vi) certain other events, including certain adverse actions taken by the FDA, CMS or other governmental authorities. Upon an event of default, the Company's obligations under the MidCap agreement may, or in the event of insolvency or bankruptcy will automatically, be accelerated.

The balance of the secured term loan due to MidCap as of December 31, 2016 is \$30 million, and is recorded in the accompanying consolidated balance sheet, net of unamortized discount and debt issuance costs.

Future minimum payments required under the term loan and the revolving line of credit as of December 31, 2016 are as follows:

(in thousands)	Term Loan
2017	\$ —
2018	1,667
2019	10,000
2020	10,000
2021	8,333
Thereafter	—
Total minimum payments	\$ 30,000

In addition to the MidCap term loan payments listed above, the Company is required to pay an exit fee of 6.0% of the aggregate principal amount of all term loan borrowings (currently equal to \$1.8 million). The 6% exit fee of \$1.8 million is being accreted to interest expense through the maturity of the MidCap loan.

The Company did not borrow under the revolving line of credit during 2016.

9. Share capital

On January 29, 2015, the Company entered into an underwriting agreement, or the Underwriting Agreement, with J.P. Morgan Securities LLC and Piper Jaffray & Co., as representatives of the several underwriters named therein, collectively, the Underwriters, relating to the public offering, or the Offering, of 4,255,319 ordinary shares, nominal value £0.006705, or the Shares, at an offering price to the public of \$11.75 per Share, or the Offering Price. The Underwriters agreed to purchase the Shares from the Company pursuant to the Underwriting Agreement at a price of \$11.045 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriters a 30-day option to purchase up to an additional 638,297 Shares, or the Option Shares, at the Offering Price, less underwriting discounts and commissions. On January 30, 2015, the Underwriters exercised their option to purchase the Option Shares in full. The gross proceeds to the Company from the sale of the Shares and the Option Shares were approximately \$57.5 million and the Company received net proceeds of approximately \$53.8 million after deducting underwriting discounts and commissions and estimated aggregate offering expenses payable by the Company. The Offering closed on February 4, 2015.

During 2016, 85,943 ordinary shares were issued upon the exercise of options. As of December 31, 2016, there were 36,183,293 ordinary shares authorized and 22,635,431 ordinary shares issued and outstanding.

10. 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. The Company currently maintains two equity compensation plans, the Amended and Restated 2008 Stock Incentive Plan and the 2013 Share Incentive Plan (the Plans). With the adoption of the 2013 Share Incentive 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 Share Incentive Plan (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 authorizes 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. At December 31, 2016, there were 2,004,074 shares available for future issuance under the 2013 Plan.

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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. Option awards to employees generally vest monthly over a four year period. 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 with 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, 2016, 2015 and 2014 was \$4.53, \$6.33 and \$9.32, 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:

	2016	2015	2014
Expected dividend yield (%)	—	—	—
Expected volatility (%)	43.70	44.11	46.87
Risk-free interest rate (%)	1.53	1.66	1.86
Expected life of option (years)	6.16	6.19	6.19
Weighted-average share price (\$)	10.29	14.15	19.66
Weighted-average exercise price (\$)	10.29	14.15	19.66
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, the Company used an average share price volatility over a historical period equal in length to the expected term, based on an analysis of reported data for a peer group of comparable companies which were selected based upon industry similarities. The Company intends to continue to use comparable companies in its volatility factor calculation 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, 2016, 2015 and 2014, a forfeiture rate of 5% was applied.

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, 2016	2,425,426	\$ 9.03
Granted	749,964	10.29
Exercised	(85,943)	0.82
Forfeited	(239,667)	14.27
Outstanding as of December 31, 2016	<u>2,849,780</u>	<u>9.15</u>
Vested or expected to vest as of December 31, 2016	<u>2,790,851</u>	<u>\$ 9.08</u>
Exercisable as of December 31, 2016	<u>1,671,179</u>	<u>\$ 6.81</u>

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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, 2016	366,739	\$ 19.72
Granted	108,361	10.21
Cancelled	(57,530)	16.17
Vested	(88,105)	22.99
Unvested balance as of December 31, 2016	<u>329,465</u>	16.34

As of December 31, 2016, there was \$5.0 million and \$3.3 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 1.9 years, respectively.

The aggregate intrinsic value of all share options outstanding under the Plans as of December 31, 2016 and 2015 was \$19.2 million and \$12.6 million, respectively. The aggregate intrinsic value of share options that were fully vested under the Plans as of December 31, 2016 was \$15.6 million.

During the years ended December 31, 2016, 2015 and 2014, current and former employees of the Company exercised a total of 85,943, 41,222 and 65,054 share options, respectively, resulting in total proceeds of \$76,000 during 2016, \$20,000 during 2015 and \$14,000 during 2014. The intrinsic value of share options exercised during the years ended December 31, 2016, 2015 and 2014 was \$1.0 million, \$0.5 million and \$0.9 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, 2015	1,124,443	\$ 6.53
Granted	749,964	4.53
Vested	(479,295)	5.92
Forfeited	(216,510)	6.08
Balance as of December 31, 2016	<u>1,178,602</u>	5.61

The total fair value of shares vested for the years ended December 31, 2016, 2015 and 2014 was \$2.9 million, \$1.9 million and \$1.0 million, respectively.

The impact on the Company's results of operations from share-based compensation for the years ended December 31, 2016, 2015 and 2014, was as follows:

(in thousands)	2016	2015	2014
Cost of revenue	\$ 57	\$ 529	\$ 330
Research and development	548	86	87
Sales and marketing	1,725	1,045	949
General and administrative	2,689	1,825	1,155
Total share-based compensation	<u>\$ 5,019</u>	<u>\$ 3,485</u>	<u>\$ 2,521</u>

For the year ended December 31, 2016, the Company incurred shared-based compensation expense related to share options, and restricted shares and RSUs of approximately \$3.2 million and \$1.8 million, respectively. For the year ended December 31, 2015, the Company incurred shared-based compensation expense related to share options, and restricted shares and RSUs of approximately \$2.4 million and \$1.1 million, respectively. For the year ended December 31, 2014, the Company incurred shared-based compensation expense related to share options and restricted shares of approximately \$1.6 million and \$0.9 million, respectively.

11. Net loss per ordinary share

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

(\$ in thousands)	Year ended December 31,		
	2016	2015	2014
Numerator:			
Net loss per ordinary share	\$ (22,349)	\$ (24,478)	\$ (22,174)
Denominator:			
Weighted-average ordinary shares outstanding-basic	22,353,713	21,781,933	17,310,148
Dilutive effect of ordinary share equivalents resulting from ordinary share options, ordinary share warrants and preferred ordinary shares (as converted)	—	—	—
Weighted-average ordinary shares outstanding-diluted	22,353,713	21,781,933	17,310,148

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 presented because their effect would have been anti-dilutive:

	Year ended December 31,		
	2016	2015	2014
Options to purchase ordinary shares	1,065,655	1,108,240	1,194,612
Unvested restricted shares and RSUs	329,465	366,739	275,500

12. Income taxes

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

(in thousands)	2016	2015	2014
Domestic (United Kingdom)	\$ (730)	\$ 1,400	\$ (158)
Foreign (United States)	(25,393)	(25,732)	(21,862)
Loss before income taxes	\$ (26,123)	\$ (24,332)	\$ (22,020)

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

(in thousands)	2016	2015	2014
Current:			
Federal	\$ —	\$ —	\$ —
U.K.	—	—	—
Japan	(85)	(116)	(119)
China	(12)	—	—
State	(51)	(30)	(35)
Total current provision	(148)	(146)	(154)
Deferred:			
Federal	752	—	—
U.K.	2,630	—	—
State	540	—	—
Total deferred benefit	3,922	—	—
Income tax benefit (expense)	3,774	(146)	(154)

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.

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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:

	2016	2015	2014
Income tax rate	20.0%	20.3%	21.5%
U.K. research and development credit	1.8	1.3	1.7
Other	(2.1)	(1.1)	(1.2)
Effect of foreign tax rate differential	16.8	10.7	17.9
Valuation allowance	(22.1)	(31.7)	(40.6)
Effective income tax rate	<u>14.4%</u>	<u>(0.5)%</u>	<u>(0.7)%</u>

The Company is headquartered in the United Kingdom and the effective U.K. corporate tax rate for the years ended December 31, 2016, 2015, and 2014 was 20.0%, 20.3%, 21.5%, respectively. The U.S. federal corporate tax rate was 34% for the years ended December 31, 2016, 2015 and 2014. 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 2013 through 2016. With a few exceptions, the Company is no longer subject to examinations by tax authorities for the tax years 2012 and prior. However, net operating losses from the tax years 2012 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 adopted a 17% tax rate in respect of the deferred tax disclosures, reflecting the anticipated timing of the unwinding of the deferred tax balances.

Significant components of the Company's deferred tax assets and deferred tax liabilities are as follows for the years ended December 31:

(in thousands)	2016	2015
Deferred tax assets:		
Long term deferred tax assets:		
U.S. federal net operating losses	\$ 42,165	\$ 32,095
State net operating loss (net of federal)	5,198	4,021
U.S. federal research and development credit	273	155
U.K. net operating loss	2,419	5,217
Share options	1,884	1,251
Accrued liabilities	526	177
State credits	85	—
Other	—	160
Total deferred tax assets	<u>52,550</u>	<u>43,076</u>
Valuation allowance	(46,473)	(43,076)
Total deferred tax assets	<u>\$ 6,077</u>	<u>\$ —</u>
Deferred tax liabilities:		
Long term deferred tax liabilities:		
Other assets	\$ (29)	\$ —
Intangible assets	(3,418)	—
Total deferred tax liabilities	<u>\$ (3,447)</u>	<u>\$ —</u>

For the years ended December 31, 2016 and 2015, the Company had United Kingdom Net Operating Losses (U.K. NOLs) of \$14.2 million and \$29.0 million, respectively. U.S. federal net operating loss carry forwards for the years ended December 31, 2016 and 2015 were \$125.3 million and \$95.5 million, respectively. U.S. State net operating loss carryforwards for the years ended December 31, 2016 and 2015 were \$112.5 million and \$85.8 million, respectively.

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The U.S. federal and state net operating loss carryforwards begin to expire in 2027 and 2016, respectively and the U.K. NOLs can be carried forward indefinitely.

For the year ended December 31, 2016, the Company recognized a deferred tax asset in the U.K. of \$2.6 million. The Company has determined that it is more likely than not that this asset 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)	2016	2015	2014
Beginning of year (January 1)	\$ 43,076	\$ 35,361	\$ 26,413
Increase in valuation allowance	3,397	7,715	8,948
End of year (December 31)	<u>\$ 46,473</u>	<u>\$ 43,076</u>	<u>\$ 35,361</u>

The Company reviewed its historical tax filings and tax positions and has determined no material uncertain tax positions exist at December 31, 2016 and 2015. The Company continues to monitor its tax filings and positions.

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, 2016, no amounts were reimbursed for research and development tax credits.

13. 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. 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 in November 2013. The Company has ongoing obligations to make certain payments to Oxford Innovation while the assigned patents remain in force in certain countries. 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, 2016 are set forth in the commitments and contingencies table in Note 15 "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 \$6.8 million, \$5.1 million, and \$4.8 million for the years ended December 31, 2016, 2015 and 2014, respectively. The Company paid other license-related expenses, including patent prosecution expenses, milestone payments and assignment fees due to these licensors, amounting to \$0.2 million, \$0.2 million, and \$0.1 million for the years ended December 31, 2016, 2015 and 2014, respectively. The aggregate royalty rate paid by the Company in the years ended December 31, 2016, 2015 and 2014, as a percentage of the gross product and service revenue of the Company, was 8%, 8% and 10%, respectively.

14. 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 \$0.2 million in matching contributions in the year ended December 31, 2016.

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 \$0.6 million in contributions in the year ended December 31, 2016, and \$0.7 million in the year ended December 31, 2015 and \$0.6 million in 2014.

15. Commitments and contingencies

Operating leases

At December 31, 2016, the Company leases facilities under six non-cancelable operating leases, with terms that expire between 2017 and 2021. The Company leases office, storage/warehouse, laboratory and manufacturing space in Abingdon, U.K., which leases are due to expire on January 31, 2025 (with respect to the storage/warehouse facility) and June 11, 2019. 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 addition, the Company leases laboratory space in Memphis, Tennessee, which lease is due to expire on December 31, 2021. The Company has an option to extend the lease for two additional terms of five years each. The two laboratory facilities acquired in 2016 are located in Norwood and Boston, Massachusetts. The Company currently leases approximately 22,000 square feet of space in Norwood and approximately 18,000 square feet in Boston. The Norwood lease expires in 2021, while the Boston lease expires in 2018. The Company's current rent under the Norwood lease is \$412,000 annually, subject to annual increases. The Company's current rent under the Boston lease is \$263,000 annually.

Future minimum lease payments required under the non-cancelable operating leases in effect as of December 31, 2016 are as follows:

(in thousands)	December 31, 2016
2017	\$ 1,945
2018	1,852
2019	1,406
2020	1,126
2021	659
Thereafter	192
Total minimum lease payments	\$ 7,180

Rent expense is calculated on a straight-line basis over the term of the lease. Rent expense recognized under operating leases totaled \$1.4 million, \$0.9 million and \$0.7 million for the years ended December 31, 2016, 2015 and 2014, 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 13, "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, 2016 are as follows:

(in thousands)	License agreements	Supplier purchase obligations	Total
2017	\$ 1,518	\$ 4,189	\$ 5,707
2018	1,512	447	1,959
2019	1,506	—	1,506
2020	25	—	25
2021	—	—	—
Thereafter	—	—	—
Total minimum payments	\$ 4,561	\$ 4,636	\$ 9,197

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.

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.

16. 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, 2016, 2015 and 2014 and the Company's long-lived assets as of December 31, 2016 and 2015.

(in thousands)	Revenue Years ended December 31,			Long-lived assets As of December 31,	
	2016	2015	2014	2016	2015
United States	\$ 49,462	\$ 31,362	\$ 22,537	\$ 6,625	\$ 5,051
United Kingdom	2,620	2,836	2,971	922	954
Europe & ROW (excluding United Kingdom)	4,368	4,231	4,248	139	170
Europe & ROW	6,988	7,067	7,219	1,061	1,124
Asia	29,628	24,353	19,749	107	109
Total	\$ 86,078	\$ 62,782	\$ 49,505	\$ 7,793	\$ 6,284

China represented approximately 44%, 46% and 43% of Asia revenue in 2016, 2015 and 2014, respectively. Japan represented approximately 55%, 53% and 54% of Asia revenue in 2016, 2015 and 2014, respectively.

17. 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 relate 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. \$1.8 million of the purchase price has been placed in escrow for a period of twelve months from the closing date to serve as security for potential indemnification claims. 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 have been finalized during the fourth quarter of 2016.

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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	<u>\$ 22,200</u>

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%. We consider 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.

Goodwill of approximately \$2.6 million represents the excess of the purchase price of the acquired business over the fair value of the underlying net tangible and identifiable intangible assets and represents the expected synergistic benefits of the transaction, which relate to an increase in future revenues for the Company as a result of leveraging Imugen's systems and expertise of its employees. The goodwill is 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. There was no evidence of any impairments at December 31, 2016 and there were no impairment charges during the year ended December 31, 2016. Goodwill related to the Imugen acquisition is deductible for tax purposes over 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 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.

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 relate to IPR&D related to a test for Babesia, fixed assets, customer relationships, the "Immunetics" trade name, Immunetics' proprietary testing technology for Lyme disease, and various government grants currently in progress.

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 next three years. Approximately \$400,000 of the purchase price is being held by the Company for a period of eighteen months from the closing date to serve as security for potential indemnification claims. The Company has determined that this liability is a Level 3 fair value measurement within the FASB's fair value hierarchy and the fair value has 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%. Such liability is adjusted to fair value at each reporting date, with the adjustment reflected in general and administrative expenses. See Note 2 "Fair value measurement" for information pertaining to changes in the fair value of this liability.

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. While the Company is close to finalization of the purchase price accounting, it has recorded provisional amounts for the assets acquired and liabilities assumed, based upon their estimated fair values at the date of the business acquisition. These provisional amounts may be adjusted as necessary during the measurement period (up to one year from the acquisition date) while the accounting is finalized. The Company paid approximately \$655,000 in transaction costs associated with this transaction, which is included in general and administrative expense in the statement of operations.

Total consideration was (in thousands):

Cash consideration	\$ 6,000
Estimated fair value of contingent consideration	3,444
Total consideration transferred	<u>\$ 9,444</u>

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The table below summarizes the purchase price of the Immunetics acquisition and the fair value of identified assets acquired and liabilities assumed at the acquisition date (in thousands):

Assets acquired:		
Cash	\$	285
Accounts receivable, net		347
Inventory, net		420
Prepaid expenses and other assets		199
Property and equipment		787
In-process research and development		6,970
Customer relationships		400
Trade name		290
Technology – clinical		860
Grants		50
Total assets acquired		<u>10,608</u>
Liabilities assumed:		
Accounts payable		(319)
Accrued liabilities		(739)
Other liabilities		(1,283)
Total liabilities assumed		<u>(2,341)</u>
Net assets acquired		8,267
Add: Goodwill		1,177
Total consideration transferred	\$	<u><u>9,444</u></u>

On the date of the acquisition, the fair value of acquired intangible assets was determined to be \$8.6 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 consider 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.

Goodwill of approximately \$1.2 million represents the excess of the purchase price of the acquired business over the fair value of the underlying net tangible and identifiable intangible assets and represents the expected benefits of the transaction, which relate to an increase in future revenues for the Company as a result of leveraging Immunetics' systems and expertise of its employees. The goodwill is 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. There was no evidence of any impairments at December 31, 2016 and there were no impairment charges during the quarter ended December 31, 2016. The goodwill recognized is not deductible for tax purposes.

Actual results of operations acquired from Immunetics are 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.

Pro Forma Information (Unaudited): The unaudited pro forma condensed consolidated statement of operations of the Company, set forth below, gives effect to the Company's acquisitions of Imugen and Immunetics as if they occurred on January 1, 2015. These amounts are not necessarily indicative of the consolidated results of operations for future years or actual results that would have been realized had the acquisitions occurred as of those dates:

(in thousands, except share and per share data)	Year Ended December 31,	
	2016	2015
Total revenues	\$ 92,860	\$ 75,622
Net loss	\$ (21,840)	\$ (25,281)
Net loss per share—basic and diluted	\$ (0.98)	\$ (1.16)
Weighted average shares outstanding—basic and diluted	<u>22,353,713</u>	<u>21,781,933</u>

Pro forma net loss for the year ended December 31, 2016, excludes \$2.7 million related to transaction costs and accelerated stock-based compensation costs incurred in connection with the Imugen and Immunetics acquisitions.

[Table of Contents](#)**Prior Year Acquisition***Boulder Diagnostics, Inc.*

On July 31, 2014, the Company acquired substantially all of the assets of Boulder, a privately owned company developing immunology-based assays for autoimmune and inflammatory conditions/diseases. The assets acquired primarily related to assays for Lyme disease and gout and an assay to help select biologics for autoimmune disease based on monitoring and prognosis of drug response that was acquired in conjunction with the Boulder acquisition. As part of the transaction, Boulder transferred to the Company all shares of capital stock in its wholly-owned subsidiary, Boulder Diagnostics Europe GmbH, such that the Company has become the sole owner of Boulder Diagnostics Europe GmbH.

The terms of the purchase agreement provided for an upfront payment of \$1.7 million and contingent purchase price consideration consisting of future potential milestone payments totaling up to \$6.1 million in respect of the Lyme disease and gout assays at any time on or prior to July 31, 2024. The milestone payments consisted of up to \$400,000 for the completion of studies related to acquired technologies, up to \$700,000 for the development of diagnostic test kits, \$500,000 for the first patient enrolled in an Institutional Review Board approved study, up to \$1.5 million for the issuance of patents, and up to \$3.0 million for approvals or clearances by the U.S. Food and Drug Administration. The Company determined that this liability was a Level 3 fair value measurement within the FASB's fair value hierarchy and the fair value was estimated to be \$1.2 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 15%. Such liability was adjusted to fair value at each reporting date, with the adjustment reflected in general and administrative expenses. See Note 2 "Fair value measurement" for information pertaining to changes in the fair value of this liability.

The acquisition of Boulder was accounted for under the acquisition method of accounting and was finalized during the fourth quarter of 2014. Total consideration was (in thousands):

Cash consideration	\$ 1,724
Estimated fair value of contingent consideration	1,247
Total consideration transferred	<u>\$ 2,971</u>

\$183,200 of the cash consideration was placed in an escrow account as security for any undisclosed liabilities and as indemnification for certain items. The Company paid approximately \$181,000 in transaction costs associated with this transaction, which was included in general and administrative expense in the consolidated statement of operations.

The following table summarizes the purchase price of the Boulder acquisition, the fair value of identified assets acquired and liabilities assumed at the acquisition date (in thousands):

Assets acquired:	
Cash	\$ 8
Accounts receivable	15
Inventory	40
Prepaid expenses and other assets	12
Property and equipment	359
In-process research and development	2,627
Total assets acquired	<u>3,061</u>
Liabilities assumed:	
Accounts payable	(97)
Accrued liabilities	(14)
Other current liabilities	(34)
Total liabilities assumed	<u>(145)</u>
Net assets acquired	2,916
Add: goodwill	55
Total consideration transferred	<u>\$ 2,971</u>

On the date of the acquisition the fair value of IPR&D acquired was determined to be \$2.6 million (\$1.8 million for the Lyme disease assay, \$0.5 million for the assay to help select biologics for autoimmune disease based on monitoring and prognosis of drug response that was acquired in conjunction with the Boulder acquisition, and \$0.3 million for the gout assay) using the excess earnings method with significant inputs, including estimates of the timing and cost required for product approval, revenue growth, gross margin, operating expenses and a 15% discount rate, that were not observable. The Company considered the fair value of IPR&D to be a Level 3 fair value asset due to the significant estimates and assumptions used by management in establishing the estimated fair value.

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Goodwill and IPR&D are indefinite-lived intangible assets and are not amortized. Rather, they are reviewed for impairment at least annually. During the third quarter of 2015, the timeline for the development of an assay to inform decisions regarding biologic therapies that was acquired as part of the Boulder acquisition was changed due to delays in the completion of research studies. Based upon the changed timeline and the resulting impact on fair value, the Company recorded an IPR&D impairment charge of \$385,000 as of December 31, 2015. During the fourth quarter of 2016, the decision was made to halt research on the GoutiFind blood test. Based on this decision, the Company recorded a non-cash impairment charge of \$270,000 to fully reserve the GoutiFind IPR&D. In addition, 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. The impairment charge has been shown on a separate line in the financial statements. Similar charges recorded in prior years have been reclassified out of research and development expense for comparative purposes.

During the fourth quarter of 2016, the Company also wrote off the GoutiFind related contingent purchase price consideration of \$901,000. In addition during the fourth quarter of 2016, the Company determined that the milestones related to the SpiroFind product would not be achieved and wrote off the contingent purchase price consideration of \$551,000 related to this product candidate.

Actual results of operations of Boulder for 2014 were included in the financial statements from the date of the acquisition, including revenues in the amount of \$42,000 and losses from operations of \$396,000. The functional currency for Boulder in Germany is the Euro.

18. Subsequent event

Effective February 24, 2017, the Remuneration Committee of the Board of Directors approved grants to employees for up to 529,096 share options and 94,989 restricted share units from the Oxford Immunotec Global PLC 2013 Share Incentive Plan. These grants were issued to employees in the first quarter of 2017.

SECOND AMENDMENT TO DISTRIBUTORSHIP AGREEMENT

THIS SECOND AMENDMENT to Distributorship Agreement (“Second Amendment”) is made this 3 day of November, 2016 by and between Oxford Immunotec Limited, a company incorporated in England with number 04516079, whose registered office is at 94C Innovation Drive, Milton Park, Abingdon, Oxfordshire OX15 4RZ (the “Company”) and Fosun Long March Medical Science Co. Ltd., (registration number Shanghai Joint-Venture 000422) whose registered office and principal place of business is both at 830 Cheng Yin Road, Shanghai, China 200444 (“Fosun Shanghai I) and Shanghai Xin Chang Medical Device Co. Ltd (registration number 310110000477786), whose registered office and principal place of business is at number 830 Cheng Yin Road, Shanghai, China 200444 (“Fosun Shanghai II”) (Fosun Shanghai I and Fosun Shanghai II are herein collectively referred to as “Distributors”).

WHEREAS,

A. The Company and Distributors are parties to a Distributorship Agreement dated 8 October 2013 (the “Distributorship Agreement”), and amended on or about 22 April 2015 (the “First Amendment”), pursuant to which Distributors were appointed to distribute Company’s Products in the Territory; and,

B. The Company and Distributors now wish to further amend the Distributorship Agreement to incorporate the terms and conditions as set forth in this Second Amendment.

IT IS AGREED as follows:

1. Except to the extent defined in this Amendment, all capitalized terms shall have the definitions provided in the Distributorship Agreement.
 2. The Parties agree that Schedule 1 to the Distributorship Agreement as set forth in the First Amendment shall be amended by deleting Subparagraph B in its entirety and replacing it with the following:
 - B. No Charge Kit Program for 2016
 1. OI agrees to provide up to [***] Kits to Distributors at no charge in 2016 for Distributors’ use in connection with Distributors promotional and discount programs (the “No Charge Kits”) so long as Distributor purchases a total of [***] Kits on or before [***] (the “2016 Sales Target”). Unless otherwise agreed by the parties, the No Charge Kits shall be delivered by OI in coordination with OI’s shipment of Kits purchased by Distributors in amounts proportionate to the purchased Kits.
 2. If the 2016 Sales Target is not met as set forth above, OI shall invoice, and Distributors shall remit payment for, the No Charge Kits at the Agreed Price of Kits.
-

THIS EXHIBIT HAS BEEN REDACTED AND IS THE SUBJECT OF A CONFIDENTIAL TREATMENT REQUEST. REDACTED MATERIAL IS MARKED WITH [***] AND HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.

Exhibit 10.20

3. Except as amended hereby, all other terms of the Distributorship Agreement shall remain in full force and effect.

IN WITNESS that this Amendment has been executed by duly authorized officers of the parties to the Agreement the day and year first above written.

For and on behalf of Oxford Immunotec Limited

Signature: /s/ Peter Wrighton-Smith

Name: Dr. Peter Wrighton-Smith

Title: CEO

Date: 14 October 2016

Place: Oxford Immunotec Office, UK

For and on behalf of Shanghai Fosun Long March Medical Science Co. Ltd.

Signature: /s/ Zhu Yao Yi

Name: Mr Zhu Yao Yi

Title: Chairman

Date: 03 November 2016

Place: Fosun, China

For and on behalf of Shanghai Xin Chang Medical Device Co. Ltd.

Signature: /s/ Zhu Yao Yi

Name: Mr Zhu Yao Yi

Title: Chairman

Date: 03 November 2016

Place: Fosun, China

Oxford Immunotec Global PLC Subsidiaries

Entity	Jurisdiction of Organization
Oxford Immunotec Limited	United Kingdom
Oxford Immunotec Inc.	Delaware
Immunetics, Inc.	Massachusetts
Oxford Diagnostic Laboratories (UK) Limited	United Kingdom
Oxford Immunotec K.K.	Japan
Boulder Diagnostics Europe GmbH	Germany
Oxford Immunotec Asia Limited	Hong Kong
Oxford Immunotec (Shanghai) Medical Device Co. Ltd.	Shanghai, China

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the following Registration Statements:

- (1) Registration Statement (Form S-3 Nos. 333-215236 and 333-200571) of Oxford Immunotec Global PLC,
- (2) Registration Statement (Form S-8 No. 333-193730) pertaining to the Oxford Immunotec Global PLC 2013 Share Incentive Plan, and
- (3) Registration Statement (Form S-8 No. 333-192582) pertaining to the Amended and Restated 2008 Stock Incentive Plan of Oxford Immunotec Global PLC;

of our report dated February 28, 2017 with respect to the consolidated financial statements of Oxford Immunotec Global PLC included in this Annual Report (Form 10-K) of Oxford Immunotec Global PLC for the year ended December 31, 2016.

/s/ Ernst & Young LLP

Reading, United Kingdom
February 28, 2017

CERTIFICATION

I, Peter Wrighton-Smith, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Oxford Immunotec Global PLC;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period for which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2017

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

Peter Wrighton-Smith, Ph.D.

Chief Executive Officer and Director

CERTIFICATION

I, Richard M. Altieri, certify that:

1. I have reviewed this Annual Report on Form 10-K of Oxford Immunotec Global PLC;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period for which this report is being prepared;
 - b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 28, 2017

/s/ Richard M. Altieri
Richard M. Altieri
Chief Financial Officer

CERTIFICATION

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), each of the undersigned officers of Oxford Immunotec Global PLC, a company incorporated in England and Wales (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report for the year ended December 31, 2016 (the "Form 10-K") of the Company fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 28, 2017

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

Peter Wrighton-Smith, Ph.D.

Chief Executive Officer and Director

Date: February 28, 2017

/s/ Richard M. Altieri

Richard M. Altieri

Chief Financial Officer

This certification is being furnished and not filed, and shall not be incorporated into any document for any purpose, under the Securities Exchange Act of 1934 or the Securities Act of 1933.

