

Quotient Ltd
Form 10-K
May 31, 2016

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 March 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 001-36415

QUOTIENT LIMITED

(Exact name of registrant as specified in its charter)

Jersey, Channel Islands
(State or Other Jurisdiction of
Incorporation or Organization)

Not Applicable
(I.R.S. Employer
Identification No.)

Pentlands Science Park

Not Applicable

Bush Loan, Penicuik, Midlothian

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EH26 0PZ, United Kingdom
(Address of Principal Executive Offices) (Zip Code)

001-44-131-445-6159

(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, nil par value	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

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 <input type="checkbox"/>	Accelerated filer <input checked="" type="checkbox"/>
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Non-accelerated filer <input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company <input type="checkbox"/>
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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 September 30, 2015, 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 \$110.8 million

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based on the closing sales price of the registrant's ordinary shares on September 30, 2015 as reported on The NASDAQ Global Market.

On May 27, 2016, the registrant had a total of 25,408,950 ordinary shares, nil par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2016 annual meeting of shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

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FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K, and exhibits thereto, contains estimates, predictions, opinions, projections and other statements that may be interpreted as “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act, that involve substantial risks and uncertainties. The forward-looking statements are contained principally in Part 1, 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. Forward-looking statements can be identified by words such as “strategy,” “objective,” “anticipate,” “believe,” “estimate,” “expect,” “intend,” “may,” “plan,” “predict,” “project,” “target,” “potential,” “will,” “would,” “could,” “should,” “contemplate,” “might,” “design” and other similar expressions, although not all forward-looking statements contain these identifying words. 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 are subject to numerous known and unknown risks and uncertainties.

Forward-looking statements include statements about:

- the development, regulatory approval and commercialization of MosaiQ™
- the design of blood grouping and disease screening capabilities of MosaiQ™ and the benefits of MosaiQ™ for both customers and patients;
- future demand for and customer adoption of MosaiQ™, the factors that we believe will drive such demand and our ability to address such demand;
- our expected profit margins for MosaiQ™;
- the size of the market for MosaiQ™;
- the regulation of MosaiQ™ by the U.S. Food and Drug Administration, or the FDA, or other regulatory bodies, or any unanticipated regulatory changes or scrutiny by such regulators;
- future plans for our conventional reagent products;
- the status of our future relationships with customers, suppliers, and regulators relating to our conventional reagent products;
- future demand for our conventional reagent products and our ability to meet such demand;
- our ability to manage the risks associated with international operations;
- anticipated changes, trends and challenges in our business and the transfusion diagnostics market;
- the effects of competition;
- the expected outcome or impact of litigation;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our anticipated cash needs and our expected sources of funding, including the achievement of product development milestones, and our estimates regarding our capital requirements and capital expenditures; and
- our plans for executive and director compensation for the future.

You should refer to Part I, 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.

PART I

Item 1. Business

Overview

We are a commercial-stage diagnostics company committed to reducing healthcare costs and improving patient care through the provision of innovative tests within established markets. Our initial focus is on blood grouping and donor disease screening, which is commonly referred to as transfusion diagnostics. Blood grouping involves specific procedures performed at donor or patient testing laboratories to characterize blood, which includes antigen typing and antibody identification. Disease screening involves the screening of donor blood for unwanted pathogens using two different methods, a serological approach (testing for specific antigens or antibodies) and a molecular approach (testing for DNA or RNA).

We have over 30 years of experience developing, manufacturing and commercializing conventional reagent products used for blood grouping within the global transfusion diagnostics market. We are developing MosaiQ™, our proprietary technology platform, to better address the needs of this large and established market. MosaiQ™ will initially comprise two separate consumables, one for blood grouping and one for serological disease screening, and a high-throughput instrument. We are also developing a third consumable for molecular disease screening. We believe MosaiQ™ has the potential to transform transfusion diagnostics, significantly reducing the cost of blood grouping in a donor or patient testing environment, while improving patient outcomes.

We have designed MosaiQ™ to offer a breadth of diagnostic tests that is unmatched by existing commercially available transfusion diagnostic instrument platforms. Time to result for MosaiQ™ will be significantly quicker than existing methods for extended antigen typing and antibody identification and is expected to be equivalent to the time to result for current instrument platforms performing basic antigen typing. We believe that customer adoption of MosaiQ™ will lead to improved patient outcomes through better and easier matching of donor and patient blood, given cost-effective extended antigen typing offered by MosaiQ™. Improved patient outcomes using MosaiQ™ include the potential for reduced incidence of alloimmunization, where the patient develops antibodies to foreign antigens introduced to the body through transfused blood. MosaiQ™ will also offer the opportunity for substantial cost savings and a range of operational efficiencies for donor and patient testing laboratories, including:

- comprehensive characterization of donor or patient blood, eliminating the need for routine manual testing typically undertaken by skilled technicians;
- simplification of required consumables and testing processes;
- consolidation of multiple instrument platforms in donor testing laboratories;
- significant reduction of sample volume requirements;
- reduction of consumable and reagent waste; and
- more streamlined processes for matching donor units to patients.

We have designed MosaiQ™ to match the existing performance of automated platforms used by donor testing laboratories for serological disease screening. We also believe the incorporation of molecular disease screening testing on MosaiQ™ will offer considerable advantages over existing approaches in use by donor testing laboratories, delivering operational cost savings and a reduced time to result, while also eliminating the need to pool samples.

Our aim is to provide donor testing laboratories with a single instrument platform to be utilized for blood grouping, if applicable, and both serological and molecular disease screening for donated red blood cells and plasma.

We have a proven track record and significant expertise in product development, manufacturing and quality assurance, uniquely tailored to the highly regulated transfusion diagnostics market. We currently derive revenue from a portfolio of products used for blood grouping, as well as whole blood controls used daily for quality assurance testing of third-party blood grouping instruments. We have introduced a range of FDA-licensed products in the United States

under the Quotient brand, which we sell directly to donor testing laboratories, hospitals and independent patient testing laboratories. We also develop, manufacture and sell conventional reagent products to original equipment manufacturers, or OEMs, such as Ortho-Clinical Diagnostics, Inc. (or Ortho), Bio-Rad Laboratories, Inc. (or Bio-Rad) and Grifols S.A. (or Grifols).

On April 30, 2014, we completed our initial public offering and issued 5,000,000 units at \$8.00 per unit. We raised net proceeds of \$37.2 million after deducting underwriting discounts and commissions, while other costs of the offering amounted to \$3.6 million. Each unit comprised one ordinary share and one warrant and each warrant permitted the holder, prior to October 26, 2015, to subscribe for 0.8 of one new ordinary share at an exercise price equivalent to \$8.80 per underlying ordinary share. On October 26, 2015, the warrants expired and were delisted. Of the 5,000,000 warrants issued, 4,981,052 were exercised prior to the expiration date

and 18,948 were cancelled on October 26, 2015. The exercise of the warrants resulted in the issuance of 3,984,823 ordinary shares and we received proceeds of \$35.1 million.

On November 25, 2014, we entered into subscription agreements with certain institutional and individual accredited investors for the private placement of 2,000,000 newly issued ordinary shares at a price of \$9.50 per share and 850,000 newly issued pre-funded warrants at a price of \$9.49 per warrant, amounting to an aggregate subscription price of approximately \$27.1 million. Each pre-funded warrant permits the holder to subscribe for one new ordinary share at an exercise price of \$0.01 per pre-funded warrant.

On January 29, 2015, we entered into a subscription agreement with Ortho-Clinical Diagnostics Finco S.Á.R.L., an affiliate of Ortho, for the private placement of 444,445 newly issued ordinary shares at a price of \$22.50 per share and 666,665 newly issued 7% cumulative redeemable preference shares, of no par value, at a price of \$22.50 per share, for an aggregate subscription price of approximately \$25 million.

On February 10, 2016, we completed a public offering of 4,444,445 newly issued ordinary shares at a price of \$9.00 per share. The net proceeds from this offering were \$36.8 million, net of underwriting discounts and other offering expenses, while the other costs of the offering amounted to \$0.8 million.

Our Market Opportunity

The global transfusion diagnostics market is large and established. Total annual product sales in this market amounted to \$2.8 billion in 2011, of which the United States accounted for \$1.3 billion of sales. Product sales comprise the sale of reagents and instruments. In 2011, we believe blood grouping accounted for \$1.2 billion of product sales, disease screening using serological methods accounted for \$0.7 billion of sales and disease screening using molecular methods accounted for \$0.9 billion of sales. We believe product sales in 2011 to the highly concentrated donor testing market accounted for approximately \$1.9 billion of sales, while patient testing accounted for the remaining \$0.9 billion of sales. Performed primarily within hospitals, the patient testing market is highly fragmented.

According to the World Health Organization, 44 million blood donations were collected globally in 2011 within 37 “high-income” countries located in North America, Western Europe and Eastern Asia. In the United States, 16 million blood donations were collected during 2011, based on data from the U.S. Department of Health and Human Services. In addition, over 20 million plasma donations are collected each year in the United States and Europe. While plasma is not subject to blood grouping, it is subject to disease screening. We estimate that over 90 million patients are blood grouped annually in the developed world, although only a small proportion of these patients actually receive a blood transfusion.

Combined, the cost of procuring and characterizing blood for transfusion represents a significant cost to the global healthcare system. The costs and expenses related to blood grouping and disease screening are typically included in the price a hospital pays for a unit of blood. In the United States, the average price paid by a hospital for a unit of red blood cells is approximately \$225. Where a hospital requests units of blood with a specific antigen profile (for patients with blood group antibodies) the average price of those antigen negative units of blood in the United States is estimated to increase by \$80 for each antigen screened. The costs and expenses related to patient blood grouping at hospitals are not specifically reimbursed by a third party payor, but typically absorbed within the reimbursement structure of a broader medical procedure. According to the Centers for Medicare and Medicaid Services 2014 laboratory fee schedule, the reimbursement rate for outpatient services associated with basic antigen typing and an antibody screen is \$36 per sample. When an antibody screen is positive, an antibody identification procedure will be undertaken on the patient sample for which the reimbursement rate is an additional \$92 per sample.

Blood grouping and disease screening techniques have remained generally unchanged for many years. Varying levels of automation are offered by existing instrument platforms, although more complex blood grouping procedures such as extended antigen typing and antibody identification are more typically undertaken manually. The need for ongoing

routine manual testing continues to impose a significant cost burden on the healthcare system.

Our Strategy

MosaiQ™ is at an advanced stage of development and commercial scale-up. Our current efforts for commercial scale-up are focused on validating the initial manufacturing system for MosaiQ™ consumables; transferring the blood grouping and initial disease screening assays from development to production; and the evaluation and validation of field trial instruments. Our current efforts for development are focused on integrating the extended serological disease screening assay panel onto a single MosaiQ™ consumable, including final assay optimization, and assay development for molecular disease screening.

We intend to simultaneously launch our MosaiQ™ blood grouping consumable into the donor and patient testing markets with our commercial partner, Ortho. We also intend to initially launch MosaiQ™ into the donor testing market with a partial serological disease screening panel comprising assays for the detection of Cytomegalovirus, or CMV, and Syphilis. We plan to follow this initial launch

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with a second serological disease screening consumable, incorporating assays for the detection of CMV; Syphilis; Hepatitis B, or HBV, comprising HBV Surface Antigen and HBV Core Antibody; Hepatitis C, or HCV; human immunodeficiency virus, or HIV, comprising HIV Type 1 and HIV Type 2; Human T-Lymphotropic Antibodies, or HTLV; and Chagas disease.

The final probe set for the blood grouping panel has been defined. During the first quarter of 2016, we continued the transfer of individual blood grouping assays from development to production, which is expected to be completed in the second quarter of calendar 2016.

During the first quarter of 2016, we transferred to production assays for the detection of CMV and Syphilis and we expect to transfer the remaining serological disease screening assays (HBV, HCV, HIV, HTLV and Chagas disease) in the fourth quarter of 2016.

During the first quarter of 2016, we completed the commissioning of the initial manufacturing system for MosaiQ™ consumables. Our planned initial manufacturing capacity is expected to be approximately 30 million consumables per year. We plan to manufacture both the MosaiQ™ blood grouping and the initial MosaiQ™ disease screening consumables for European field trials in the second quarter of 2016.

Six out of a planned fourteen MosaiQ™ field trial instruments have now been built by our development partner, STRATEC biomedical AG. Two of these instruments have been delivered to us for evaluation. Remaining efforts are focused on software development, assay integration and validation of the instrument for field trials. The field trial instruments will be subject to final software development, which we expect to complete in the second quarter of 2016, prior to the commencement of field trials. We expect to conduct an internal validation study of the MosaiQ™ blood grouping consumable and initial MosaiQ™ serological disease screening consumable using MosaiQ™ instruments prior to commencing field trials.

The MosaiQ™ consumables will be subject to CE-marking in Europe and the instrument will be self-certified. In the United States, the FDA has indicated that the MosaiQ™ blood grouping consumable will be subject to a biologics license application, or BLA, and the MosaiQ™ instrument will be subject to a 510(k) filing. The initial serological disease screening consumable, comprising tests for CMV and Syphilis, will be subject to a 510(k) filing, while the more comprehensive serological disease screening consumable will be subject to BLA approval. The instrument is expected to be classified as a Class II medical device.

We expect to commence field trials in Europe for both the MosaiQ™ blood grouping and initial MosaiQ™ serological disease screening consumables in the third quarter of 2016. We expect to file necessary regulatory submissions for Europe in the fourth quarter of 2016 to obtain required marketing clearances for MosaiQ™. Field trials in the United States are expected to commence in the fourth quarter of 2016 and regulatory submissions are planned to be filed in the first half of 2017 to obtain required marketing clearances in the United States. Field trials for the second serological disease screening consumable are expected to commence in the first half of 2017, both in Europe and in the United States.

We expect to begin marketing MosaiQ™ in Europe during the fourth quarter of 2016. If approved for sale, we anticipate commercial launch in the United States in the first quarter of 2018. We also anticipate commercial launch of the second MosaiQ™ disease screening consumable in Europe during the second half of 2017 and in the United States during 2018, if approved for sale.

In addition, we intend to:

- continue to engage and collaborate with our key potential customers on the design and functionality of the MosaiQ™ instrument;
- continue our dialogue with regulators to obtain required regulatory licenses and clearances;

build a highly focused sales and support infrastructure to successfully commercialize MosaiQ™ for the donor testing market in North America, the European Union and certain territories in the Asia-Pacific region; and continue to collaborate with Ortho, our commercial partner for the global patient testing market. For additional information, see “—Sales, Marketing and Distribution—Ortho Clinical Diagnostics”.

In our conventional reagent business, we intend to continue to strengthen the Quotient brand, expand our customer base, reinforce our relationship with the FDA and other key regulators, continue to service our key OEM customers and expand the number of conventional reagent products we offer directly for sale in the United States.

Blood Grouping

Prior to blood transfusion, or when there is likelihood that a blood transfusion might be required, extensive blood grouping procedures are undertaken on patient and donor blood using in vitro diagnostic products. These procedures ascertain the blood group of the

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patient and ensure the compatibility of donor blood. The testing regime is designed to prevent transfusion reactions, which can range from mild to fatal.

Red blood cells (the cellular portion) and plasma (the fluid portion) are the principal components of blood. On the exterior of red blood cells are antigens that determine an individual's blood group (A, B, AB, O), or ABO group, and type (RhD positive or RhD negative), or Rh type. In addition, there are a further 32 clinically significant blood group antigens that may be present on patient and donor red blood cells. Plasma contains many different kinds of proteins, including: (i) naturally occurring blood group antibodies; (ii) blood group antibodies developed by the body in response to foreign red blood cell antigens introduced during transfusion (alloantibodies); or (iii) blood group antibodies developed following pregnancy. Blood group antibodies mirror the antigen families that are present on red blood cells. In its normal state, blood does not contain antibodies that will react with its own red blood cell antigens (autoantibodies).

Because of the potential for a transfusion reaction, it is crucial that clinicians correctly identify the blood group antigens or antibodies present in donor and patient blood prior to transfusion. If a donor's red blood cells contain antigens that are recognized by and react with existing blood group antibodies in the patient's plasma, the transfused red blood cells could be destroyed in a potentially life-threatening reaction. The identification of blood group antigens on donor and patient red blood cells is typically referred to as blood typing or basic antigen typing, with a more comprehensive characterization being referred to as extended antigen typing. The identification of blood group antibodies in plasma is typically referred to as antibody identification.

All patients potentially requiring a blood transfusion will generally be blood grouped, including pregnant women, cancer patients undergoing chemotherapy, patients undergoing surgery or patients suffering from chronic diseases that require regular blood transfusions, such as thalassemia or sickle cell disease.

Patient blood will typically be subject to a basic antigen typing and an antibody screen. Less than 1% of patients that have not received a blood transfusion will screen positive for an antibody. The incidence of blood group antibodies, however, increases significantly to 3 to 8% in patients who have previously received a blood transfusion and women that have given birth to two or more children. When an antibody screen proves positive, a complex and time consuming procedure will be performed by skilled technicians to identify all clinically significant blood group antibodies in the patient's plasma. This largely manual process may take two to six hours to complete, although more complex cases can take one or more days to complete. Antibody identification represents a significant cost to hospitals, particularly those that treat large numbers of chronically transfused patients. Reagents used for antibody identification also have a short shelf life, typically being shipped on a 28-day cycle, making management of blood grouping reagent inventories more complex with increased waste.

The increasing incidence of alloantibodies developing in patients who have received multiple transfusions, commonly referred to as alloimmunization, has prompted clinicians to request costly, extended antigen matching of donor blood for at-risk patient groups, such as those suffering from thalassemia or sickle cell disease. The incidence of antibodies present in these patient groups is estimated to be 20 to 30%. These patients typically also present with multiple antibodies, making the process of antibody identification more complex and time consuming and the procurement of antigen specific units of donor blood much more expensive.

According to a study published in January 2014, the estimated total cost of extended antigen typing for patients is \$364, based on a screen for 14 antigens at an estimated cost of \$26 per antigen.

Donor blood will typically be subject to a basic antigen typing and an antibody screen. Clinicians will request specific antigen negative donor blood for patients with one or more blood group antibodies. In this instance, multiple donor units will be selected from inventory by the donor collection agency and subjected to an extended antigen typing procedure to select the most appropriate units for the patient. This procedure is completed to ensure that the corresponding antigen to the patient's antibody is not present on the donor's red blood cells.

The number of donor units that need to be screened to identify specific antigen negative units varies depending upon blood group. In the Caucasian population, for example, ten donor units on average would need to be screened to find two units of donor blood negative for the Duffy-A antigen. Similarly, to identify two units of donor blood negative for the little-e antigen, one hundred donations would need to be screened and, to identify two units of blood negative for the little-k antigen one thousand donations would need to be screened. Additionally, the numbers of units needed to be screened increases significantly if the patient has two or more antibodies.

The identification of antigen negative units of blood is largely a manual and labor-intensive process. Because of the additional testing procedures required and the large numbers of donor units that must be screened, antigen negative donor units are more expensive for hospitals to purchase. The average premium charged for antigen negative units of blood in the United States is estimated to be \$80 for each antigen screened.

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We believe both donor collection agencies and hospitals would prefer to fully characterize donor units and patient blood through extended antigen typing prior to transfusion, although the time and expense required to undertake such procedures is currently prohibitive. As a consequence, extended antigen typing is only undertaken as needed (i.e., where the patient has a specific antibody) on a small percentage of donor units. Extended antigen typing for patients is also typically undertaken only in patients expected to be chronically transfused.

Disease Screening

The safety of donor blood is ultimately the responsibility of donor collection agencies, with regulatory agencies in individual countries establishing safeguards and standards to ensure patient safety. In the developed world, donor blood is subject to mandatory screening for infectious diseases before it can be released to hospitals. Two different methods of testing have been adopted—a serological approach (testing for specific antigens or antibodies) and, for certain viruses, a molecular approach (testing for DNA or RNA). The United States, many countries in Western Europe and Japan require both serological and molecular disease screening be performed on donor blood. In the United States, it is mandatory to screen donor blood using serological techniques for the following: Syphilis, HBV Surface Antigen, HBV Core Antibody, HCV Antibody, HIV Type 1 and Type 2 Antibodies and HTLV Antibodies. Most blood collection agencies will also screen for CMV, using the same serological approach and the FDA recommends donor blood to be screened for Chagas disease. Molecular disease screening is required to be performed on donated blood to screen for HBV, HCV, HIV and West Nile virus. Other pathogens, such as Babesia, Dengue and Malaria are transmissible by blood, but there is no test currently available, given cost or technology limitations.

Serological and molecular disease screening is already largely automated. However, it is typically undertaken using instrument platforms that are not integrated with commonly used blood grouping instruments. Automation platforms for serological disease screening have been on the market for many years, but lack many of the attributes users benefit from in other diagnostic fields, such as graphical user-interface, remote diagnostics, links to laboratory automation systems and software compatibility with laboratory information systems. Existing disease screening platforms also lack the ability to easily incorporate additional tests as the market and regulators dictate.

Donor Testing

In the developed world, the testing of donated blood is primarily completed by donor collection agencies. In the United States, two agencies, the American Red Cross and Creative Testing Solutions, test approximately 70% of all blood donations collected. Throughout Western Europe, Japan, Australia and Canada, national collection agencies, or a small number of regional collection agencies, typically collect and test all donated blood. Currently, donor testing laboratories must adopt multiple instrument platforms, as well as undertake complex manual testing procedures for extended antigen typing or antibody identification, to complete the required testing for donated blood. Maintaining multiple instrument platforms requires complex quality control and assurance procedures, along with costly service and support infrastructures.

Single instrument platforms for each testing procedure have typically been adopted within and across laboratory networks. In addition, donor testing laboratories typically utilize costly manual testing techniques to identify antigen negative donor units and to carry out any antibody identification procedures required.

Patient Testing

Patients are typically blood grouped in hospitals. Large-to-medium hospitals will generally adopt one of several semi-automated instrument platforms to perform basic blood grouping procedures. These instruments employ either column agglutination technology supplied by companies such as Ortho, Bio-Rad and Grifols, or solid-phase microplate technologies supplied by companies such as Immucor. These platforms offer only a limited number of blood grouping tests per testing run and are therefore cumbersome, especially if a more comprehensive characterization of the patient's blood is required. Consequently, laboratories that have adopted a blood grouping

instrument platform will continue to use manual or semi-manual techniques to undertake more complex procedures, such as antibody identification or extended antigen typing.

Because of the continued need for manual testing, many small to medium-sized hospitals choose not to adopt existing instrument platforms. Instead, they will use manual or semi-manual techniques for basic blood grouping. Complex procedures, such as antibody identification, may also be outsourced to independent testing laboratories by these hospitals. We believe the continued requirement for manual testing and drawbacks of existing instrument platforms for blood grouping have limited the attraction of offering blood grouping services to hospitals by large independent testing laboratories, such as LabCorp and Quest Diagnostics.

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The MosaiQ™ Solution for Transfusion Diagnostics

We are initially developing MosaiQ™ to address the comprehensive needs of the global transfusion diagnostics market. We believe MosaiQ™ has the potential to transform transfusion diagnostics by substantially reducing costs and offering a range of operational efficiencies within donor and patient testing laboratories, while improving patient outcomes through the more complete characterization of donor and patient blood.

Specifically, we are initially developing MosaiQ™ to:

- Comprehensively characterize donor and patient blood; and
- Screen donor blood for specific viruses using serological and molecular methods.

We intend to pursue a “razor/razor blade” business model for MosaiQ™, placing instruments and securing long-term agreements for the supply of blood grouping and/or disease screening consumables used by those instruments. We expect donor and patient laboratories to adopt MosaiQ™ because it is designed to offer a comprehensive characterization of clinically significant blood group antigens and antibodies, while also offering the opportunity for substantial cost savings and a range of operational efficiencies. We believe these customers would prefer to more fully characterize the blood of all donors and patients to facilitate better blood matching. While MosaiQ™ is designed to be a highly cost-effective solution for our customer, delivering substantial cost savings, we also expect to generate attractive, long-term profit margins on the sale of MosaiQ™ consumables.

We have designed MosaiQ™ leveraging our expertise in transfusion diagnostics. MosaiQ™ combines novel manufacturing techniques and well-characterized blood grouping and disease screening tests to create a multiplex testing consumable for use on a high-throughput instrument. Through miniaturization, we are combining a full portfolio of existing serological tests on two distinct consumables for use on MosaiQ™ – one for blood grouping and one for serological disease screening. We are also developing a third consumable for molecular disease screening. In a donor testing environment, the blood grouping and serological disease screening consumables have been designed to run simultaneously, utilizing the same donor sample and the same MosaiQ™ instrument. In a patient testing environment, only the blood grouping consumable would be utilized.

Our novel approach incorporates existing, well-characterized tests for blood group antigens and antibodies on a single consumable for the global market. Each MosaiQ™ consumable will consist of two protein microarrays – one for antigen typing (comprising printed monoclonal or polyclonal antibodies) and one for antibody identification (comprising printed human red blood cells). We believe MosaiQ™, when launched, will be the only commercially available automation platform capable of offering this breadth of testing on a single consumable.

The serological disease screening consumable is being designed to incorporate all tests required to meet current regulatory requirements in the markets in which we operate for serological disease screening of donor blood. We are including tests to screen serologically for Syphilis, HBV, HCV, HIV and HTLV, along with tests for CMV and Chagas disease. The disease screening consumable has additional capacity to incorporate further disease screening tests.

The molecular disease screening consumable is being designed to incorporate all tests required to meet current regulatory requirements in the markets in which we operate for molecular disease screening of donor blood. We are including molecular tests to screen for HBV, HCV, HIV and West Nile virus.

MosaiQ™ consumables will be manufactured using a novel, patented printing technology we have further developed with The Technology Partnership, or TTP, a leading European technology development company. This print technology enables us to industrialize the MosaiQ™ consumable manufacturing process. We are not aware of any alternative technology suitable and commercially available for this purpose.

We are developing a high-throughput, floor standing MosaiQ™ instrument for use by both donor collection agencies and medium to large-sized hospitals. The MosaiQ™ instrument is being designed to process up to 3,000 consumables per day (assuming three eight-hour shifts), giving a capacity to test up to 1,500 donor samples (utilizing a blood grouping consumable and a serological disease screening consumable) or 3,000 patient samples (blood grouping only). The instrument is expected to complete the comprehensive characterization of donor or patient blood in less than 35 minutes and to have the capability to prioritize urgent patient sample testing, commonly referred to as STAT testing.

The MosaiQ™ instrument is designed to fully automate blood grouping and perform a simultaneous serological disease screen in a donor testing laboratory. Consistent with the typical workflow of donor or patient testing laboratories, centrifuged tubes of whole blood will be placed on the MosaiQ™ instrument for processing. The instrument will then complete a comprehensive blood group characterization of each sample, combined with a parallel serological disease screen in a donor testing environment, with the results being reported through existing laboratory information management systems (or LIMS).

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We have partnered with STRATEC, a leading global developer of diagnostics instruments, to design, develop and manufacture the MosaiQ™ instrument. STRATEC has been operating for over 30 years and has significant experience designing, developing and manufacturing in vitro diagnostics instruments, including a number of existing instruments used today for blood grouping and disease screening. Six field trial instruments have been built for us by STRATEC for evaluation and validation purposes, with a further eight field trial instruments to be built prior to commencing field trials in Europe and the United States.

We are also collaborating with key potential donor and patient testing customers on the development of MosaiQ™. This group includes the American Red Cross and Creative Testing Solutions, along with several other major hospitals, donor collection organizations and reference laboratories.

Our Conventional Reagent Business

We have over 30 years of experience in the development, manufacturing and commercialization of conventional reagent products for blood grouping. Our conventional reagent products are used primarily to identify blood group antigens and antibodies in donor and patient blood and to perform daily quality assurance testing for third-party blood grouping instrument platforms. We also undertake product development projects for our OEM customers, generating product development fees. Following development, we enter into long-term supply contracts with our OEM customers to manufacture and supply the products we have developed.

We currently develop, manufacture and commercialize the following key products:

Antisera Products —These products contain antibodies used to identify blood group antigens. The majority of our antisera products are monoclonal antibodies manufactured from master cell lines we own;

Reagent Red Blood Cells —These products are composed of human red blood cells formulated to enable the identification of blood group antibodies. We source human red blood cells with the desired antigen profiles globally, primarily from donor collection organizations;

Whole Blood Controls —We are an industry leader in the development and manufacture of whole blood control products, with a significant relationship with Ortho and other major OEM customers. These products contain both human red blood cells and antisera specifically formulated for use as daily quality assurance tests on third-party blood grouping instrument platforms; and

Ancillary Products —These products and solutions are used to support blood grouping, but are not directly involved in blood group determination. They include Anti-Human Globulin, enhancement media, and kits for training and staff certification.

We manufacture our conventional reagent products at our Edinburgh, Scotland manufacturing facility using our own cell lines or from raw materials purchased from a limited number of suppliers. We believe we have good relationships with our suppliers. We plan to replace and expand our existing facility in Edinburgh for the development and manufacture of conventional reagent products. The new facility will be leased, although we expect its design and completion to be largely funded by us.

Our Customers

In the United States, we currently offer directly to our customers a portfolio of 38 conventional reagent products focused on blood grouping and we have over 21 additional products at various stages of development or FDA licensing. Conventional reagent products sold in the United States under the Quotient brand include antisera products, reagent red blood cells and other ancillary products. We currently serve over 900 hospitals, donor collection agencies and independent testing laboratory customers throughout the United States. Global direct sales, including sales to distributors, accounted for 32% of our product sales in the year ended March 31, 2016 and 30% in the year ended March 31, 2015.

We sell the majority of our conventional reagent products to our OEM customers for use with their blood grouping instruments as specific tests or controls. Products sold to OEM customers range from bulk material incorporated into the customer's own products to finished, vialled products sold under our customer's label. We retain ownership of the intellectual property for these finished, vialled products and their associated regulatory licenses. OEM customers accounted for 68% of product sales in the year ended March 31, 2016 and 70% in the year ended March 31, 2015. We have long-standing relationships with three leading global transfusion diagnostics companies: Ortho, Bio-Rad and Grifols.

We have developed several conventional reagent products launched by Ortho over the past five years. As a result, Ortho accounted for 57% and 55% of our product sales in the years ended March 31, 2016 and 2015, respectively. We are currently developing a range of rare antisera products for use on Ortho's instrument platforms. In May 2013, the first 14 of these products received CE-Marking for sale in Europe and we filed a BLA to obtain FDA approval for these products in 2014. We also sell a range of whole blood control

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products, red blood cell products and ancillary products to Ortho worldwide, many of which have been launched over the past five years.

MosaiQ™ Manufacturing and Supply

We have leased factory space at a manufacturing facility located in Eysins, Switzerland (near Geneva), which we expect will become the principal manufacturing site for MosaiQ™ consumables. Conversion of this facility to manufacture MosaiQ™ consumables is substantially complete and we have installed the final elements of the initial manufacturing system. Formal validation of the initial manufacturing system at the Eysins facility is expected to be completed during the second quarter of 2016.

The Technology Partnership plc (“TTP”)

We have entered into a master development agreement with TTP to design, build, install and validate the initial manufacturing system for the MosaiQ™ consumables being installed at our Eysins, Switzerland facility. TTP has agreed to certain development work programs for each phase of the design and build process and we have agreed to pay for all development costs, including costs of materials, third party costs and specified professional fees for the time of TTP’s engineers and scientists. The agreement does not have a defined term and will terminate following delivery and validation of the initial manufacturing system. Either party may terminate the agreement for certain breaches by the other party or in the event of certain bankruptcy events involving the other party. In addition, we may terminate the agreement upon 30 days’ notice for any reason. Upon termination of the agreement, we are responsible for paying any unpaid development and other costs of TTP.

We have entered into an exclusive, royalty-bearing, worldwide license with TTP to certain patented technologies and trade secrets to enable high volume manufacturing of MosaiQ™ consumables. Pursuant to this license agreement, we are paying TTP a \$10 million license fee (the TTP License Fee), which is payable in installments through March 2019. The first installment was paid on March 30, 2015. The license is for uses that include antigen typing, antibody detection and serological screening of donated blood for infectious diseases (collectively, the initial purpose), as well as all human blood sample diagnostic testing on batch processing instruments (collectively, the additional purposes), with the exception of companion diagnostics, epigenetics and nucleic acid sequencing. We will pay a low single digit royalty to TTP based on our net sales for 20 years or for so long as the licensed intellectual property is protected by patent in the country of sale. If the TTP License Fee payments are not made by us when due, we will lose the license to the additional purposes, but not to the initial purpose.

TTP has also granted us a non-exclusive, fully paid, royalty-free, perpetual, irrevocable, worldwide license to use certain other intellectual property TTP owns and has incorporated into bespoke components of the manufacturing system for MosaiQ™ consumables. The agreement will remain in effect so long as the licensed intellectual property is subject to patent or other intellectual property protection. TTP may terminate the agreement if we assist another party in disputing the validity and/or scope of any of TTP’s patented intellectual property covered by the agreement. Either party may terminate the agreement with immediate effect by notice to the other party upon the occurrence of bankruptcy events. Any fee disputes are subject to mandatory dispute resolution.

STRATEC Biomedical AG

We have entered into a development agreement with STRATEC pursuant to which it will develop a high-throughput instrument for MosaiQ™. STRATEC has agreed to a project development timeline that runs through July 31, 2016. STRATEC’s fees under this agreement total €13.1 million in aggregate, or \$14.9 million using exchange rates on March 31, 2016, payable upon completion of pre-agreed project development milestones. As of March 31, 2016, we have incurred expenses related to this agreement totaling €9.5 million, or \$10.8 million, using exchange rates on March 31, 2016. The agreement does not have a defined term. Either party may also terminate the agreement for certain breaches by the other party or in the event of certain bankruptcy events involving the other party. Upon termination by

STRATEC in connection with our breach or bankruptcy, certain termination payments are payable by us depending upon the stage of completion of the development program at the time of termination, and we are also responsible for certain costs.

We have also entered into a manufacturing agreement with STRATEC pursuant to which we will be required to purchase a fixed minimum number of high-throughput instruments during the six years following delivery of the first field trial instruments (the sixth development milestone). Our aggregate obligation under this agreement will total €51.8 million, or \$58.8 million using exchange rates on March 31, 2016. The agreement is terminable by either party for certain breaches by the other party or in the event of certain bankruptcy events involving the other party. If STRATEC terminates the manufacturing agreement, certain termination payments are payable by us depending upon the number of the instruments purchased at the time of termination, and we are also responsible for certain costs.

Pursuant to the development agreement, STRATEC has granted us an irrevocable, fully-paid, perpetual, royalty-free, worldwide license to intellectual property that is developed for use by, or the manufacture of, the MosaiQ™ instrument, as well as an exclusive

right to market and sell the MosaiQ™ instrument. STRATEC has additionally granted us, or agreed to grant, similar rights to its pre-existing technologies for use in development and manufacturing activities for the MosaiQ™ instrument. We may only exercise our rights to manufacture in limited circumstances when STRATEC fails to perform under the manufacturing agreement and such rights are subject to a to be negotiated license fee. Upon termination of the development agreement by STRATEC, the licenses granted under the development agreement will be null and void.

SCHOTT Technical Glass Solutions GmbH

On March 27, 2014, we entered into a supply agreement with SCHOTT Technical Glass Solutions GmbH, or SCHOTT, pursuant to which we will purchase minimum quantities of coated glass in connection with the development of the MosaiQ™ consumable through April 2017. The total purchase obligation under this agreement is €9.4 million, or \$10.7 million using exchange rates on March 31, 2016. As of March 31, 2016, we have made purchases from SCHOTT totaling €6.5 million, or \$7.4 million, using exchange rates on March 31, 2016. In the event we have not purchased the required quantities during any calendar year, we are obligated to pay SCHOTT a minimum commitment, which in aggregate amounts to €7.3 million, or \$8.3 million using exchange rates on March 31, 2016.

Quality

Our quality function (composed of quality assurance, quality control and validation) oversees the quality of our manufacturing as well as the quality systems used in research and development and sales and marketing. We have established a control system that oversees implementation and maintenance, document control, supplier qualification, corrective and preventative actions, as well as employee training processes that we believe ensures quality across our operations. We continuously monitor and seek to improve quality over time and believe the implementation of these processes has supported product performance, customer satisfaction, and a culture of continuous improvement.

Sales, Marketing and Distribution

We market our conventional reagent products directly in the United States. Outside of this territory, we sell our products to a range of third-party distributors and customers. In the United States, we use a combination of sales managers, sales representatives, customer service staff and technical experts to interact with laboratory managers and administrative staff, purchasing directors, medical directors and other individuals and groups involved in the implementation of blood testing programs. Our goal is to educate these groups about the technical and economic benefits of switching from competing offerings to our products. Our customer service staff and technical experts are also involved in the practical training of customers, as well as answering customer questions. These teams are supported by various marketing activities, which include advertising, medical education, attendance at scientific meetings and other awareness-raising activities. As of March 31, 2016, we had thirteen employees engaged worldwide in sales, marketing and customer service functions.

Ortho-Clinical Diagnostics

On January 29, 2015, we entered into a distribution and supply agreement with Ortho (the Ortho Agreement) to sell and distribute MosaiQ™ within the \$2.8 billion global transfusion diagnostics market. We have retained all rights to commercialize MosaiQ™ in North America, the European Union and certain Asia-Pacific territories (excluding Japan) for the donor testing market. Pursuant to the Ortho Agreement, and for an initial term of 20 years, Ortho will exclusively commercialize MosaiQ™ for the global patient testing market (for blood grouping), as well as the donor testing market (for blood grouping and serological disease screening) in territories other than those in which we will commercialize MosaiQ™. We will be responsible for the manufacture of all products (instruments, consumables and ancillary products) associated with MosaiQ™ and have retained all other commercial rights to MosaiQ™. Ortho has a right of first offer where we decide to commercialize MosaiQ™ with a third party for an application other than blood grouping. We have also agreed with Ortho to explore opportunities to develop and commercialize MosaiQ™ in other diagnostics applications outside of blood grouping and serological disease screening, utilizing the combined

knowledge and expertise of both parties.

Ortho has agreed to pay us certain one-time payments upon the achievement of regulatory and commercial milestones totaling in the aggregate \$59 million. These milestones primarily relate to the approval and launch of MosaiQ™ in the United States and the European Union for blood grouping. Ortho has also agreed to reimburse us for the cost of goods sold incurred for MosaiQ™ instruments and associated replacement parts sold to Ortho, as well as the cost of ancillary products sold to Ortho. A transfer price mechanism for MosaiQ™ consumables sold to Ortho has also been established, which will increase as a percentage of net sales based on agreed-upon revenue milestones. In addition, a basis for calculating minimum transfer prices for MosaiQ™ consumables, instruments and ancillary products has also been agreed.

As part of the exclusive sale and distribution rights granted to Ortho for the MosaiQ™ instruments and consumables (which rights are non-assignable except as provided for in the distribution and supply agreement) we have granted to Ortho: (i) an exclusive, license to

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use the “MosaiQ” trademark; (ii) access to CE-Mark, biologics license application and 510(k) clearances and other dossiers to be filed or that are approved by regulatory authorities for the MosaiQ™ instrument, consumables and ancillary products; (iii) access to other confidential information; and (iv) intellectual property rights controlled by the Company as well as intellectual property rights granted to us by STRATEC and TTP, and rights we may control in the future, which are necessary or reasonably useful for the sale and distribution of MosaiQ™ instruments and consumables and are freely licensable or sub-licensable and free of royalty or other payments (unless Ortho agrees to pay any such royalties or payments). Ortho may not use these intellectual property rights and information to manufacture the MosaiQ™ instrument or consumables, supply serological screening consumables to the patient testing market, or to carry out research and development, other than with our consent or pursuant to the distribution and supply agreement. Ortho will grant us a license for the term of the distribution and supply agreement for any know how related to the MosaiQ™ instrument and consumables that Ortho generates during the course of the distribution and supply agreement, which is necessary or useful for the development, use or sale of the MosaiQ™ instrument and consumables, or components thereof, or for us to provide maintenance and support.

Research and Development

Our research and development efforts are focused on the development of MosaiQ™ and new conventional reagent products. We believe we have assembled an experienced research and development team with the scientific talent needed to develop new products that leverage our significant blood grouping expertise. We believe our experience in developing tests based on existing serological testing methods will allow us to conceive, develop and validate comprehensive multiplex tests utilizing MosaiQ™.

As of March 31, 2016, we had 168 employees engaged in research and development functions.

Customer Funding and Reimbursement

In the United States, our products are not directly subject to reimbursement by governmental or commercial third party payors for health care services. The costs and expenses related to donor blood grouping and disease screening are typically included in the price to a hospital of a unit of blood. The costs and expenses related to patient blood grouping at hospitals are not specifically reimbursed by a third party payor, but absorbed within the reimbursement structure of a broader medical procedure. We supply products to our customers, including hospitals, donor testing laboratories, independent testing laboratories and OEM customers based on negotiated prices.

Competition

In the past 10 to 15 years, the transfusion diagnostics market has experienced considerable consolidation, particularly in the United States. Given significant barriers to entry, there are only a small number of vendors currently addressing this market. These vendors can be divided into four groups: (i) those offering instrument platforms for blood grouping and related consumables, in addition to conventional reagent products for manual testing; (ii) those only offering conventional reagent products for manual blood grouping; (iii) those offering raw materials for inclusion in products used on instrument platforms for blood grouping and in conventional reagent products; and (iv) those offering instruments for disease screening and related consumables. A small number of donor collection agencies continue to manufacture a limited range of products, primarily for internal use.

In our view, barriers to entry for the transfusion diagnostics market include:

- the need to manufacture a broad range of complex antisera products, with annual volume requirements ranging from hundreds of milliliters to hundreds of liters, depending upon individual blood group specificities;
- the ability to reliably procure and formulate red blood cell donations with the appropriate antigen profiles to support the manufacture of red blood cells for antibody identification and whole blood control products;
- rigorous global regulatory requirements; and

customers who can be reluctant to change product suppliers.

Our principal competitors in the United States are Immucor, Ortho and Grifols. The principal market participants in Europe are Bio-Rad, Ortho, Grifols and Immucor and the principal market participants in Japan are Ortho and Immucor.

For serological disease screening, only two vendors have instruments approved for sale in the United States – Abbott and Ortho. Outside the United States, Abbott, Ortho, Roche and Bio-Rad are the principal instrument providers for serological disease screening.

For molecular disease screening, only two vendors have instruments approved for sale in the United States – Grifols and Roche. Outside the United States, Grifols and Roche are the principal instrument providers for molecular disease screening.

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For products sold to OEM customers, the cost of switching vendors (raw material and/or finished costs) can be considerable, given regulatory scrutiny of the manufacturing process and the potential need to modify instrument platforms and software. For our OEM business, we consider Merck/Millipore and Diagnostics to be our primary competitors. We are also a customer of each of these two organizations. We believe the complexity and high cost of switching suppliers, together with our ownership of key products and associated regulatory licenses, reduce the risk of loss of our important OEM business. We believe the FDA-licensed status of our manufacturing facility also offers major benefits as our key OEM clients seek to either establish or defend their position in the United States market.

Intellectual Property

We have relied, and expect to continue to rely, on various exclusive and non-exclusive license agreements, granting rights to patent-protected technologies relating to the manufacture of MosaiQ™ consumables and instruments. We have entered into an exclusive license with TTP to patented technologies to enable high volume manufacture of MosaiQ™ consumables. In addition, STRATEC has agreed to grant us licenses to certain of its pre-existing technologies and has granted us licenses to technologies developed under our development agreement with it, for use in the sale of MosaiQ™ instruments, and in the development and manufacture of the MosaiQ™ instrument, which it will undertake on our behalf. See “Business— MosaiQ™ Manufacturing and Supply—The Technology Partnership plc” and “—STRATEC Biomedical AG” for additional information about these agreements. These licenses are material to the development and commercialization of MosaiQ™. The remaining lives of the patents for key existing technologies that we have licensed currently exceed 10 years.

We have an issued U.S. patent related to blood typing that expires in September 2027. This patent provides methods of detecting the presence of red blood cells coated (or sensitized) with host antibody and/or components of the complement system. We received counterpart patents for this U.S. patent in Europe, Australia and Japan, which also expire in September 2027, and filed a counterpart patent application in Canada in September 2007, which is currently pending.

In February 2014, we filed a new UK patent application providing for a new method for detecting red blood cells, also using MosaiQ™. The technology finds particular application in immunological assays where it can be used as the basis of positive controls to confirm the addition of red blood cells.

We also rely upon copyright protection, trade secrets, know-how, continuing technological innovation and licensing opportunities to develop and maintain our competitive position. Our success will depend in part on our ability to obtain patent protection for our products and processes, to preserve our copyrights and trade secrets, and to operate without infringing the proprietary rights of third parties.

We have developed several conventional reagent products launched by Ortho over the past five years. We generally retain ownership of the intellectual property for these products and their associated regulatory licenses.

Government Regulation

In the United States, medical products are subject to extensive regulation by the U.S. Food and Drug Administration, or the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, the Public Health Service Act, or the PHSA, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of medical products. Prior to marketing certain medical products, manufacturers are required to obtain permission from the FDA via a product approval or clearance. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to file submissions, refusal to approve or clear products, warning or untitled letters, product recalls, field actions, product seizures, total or partial suspension of production or distribution, refusal to permit the importation of product, injunctions, fines, civil penalties, and criminal prosecution.

The FDA regulates in vitro diagnostic, or IVD, products intended to evaluate blood as either biological products or medical devices. In general, reagents used to identify blood types, including extended antigen typing, and detect and identify antibodies in plasma, as well as assays intended for disease screening of the blood supply are regulated as biological products, while the instruments that conduct the analyses and quality assurance products intended to test the accuracy of instrument platforms are regulated as medical devices.

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 not part of the EEA and have voluntarily adopted laws and regulations that generally 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

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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 United States and 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. The process in these 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.

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.

Executive Officers

Below is a list of the names, ages as of March 31, 2016 and positions, and a brief account of the business experience of the individuals who serve as our executive officers.

Name	Age	Position
Paul Cowan	55	Chairman & Chief Executive Officer
Jeremy Stackawitz	41	President
Edward Farrell	46	President
Stephen Unger	46	Chief Financial Officer
Roland Boyd	59	Group Financial Controller & Treasurer

Paul Cowan, Chairman & Chief Executive Officer

Paul Cowan is our Chief Executive Officer and Chairman of our Board of Directors. Mr. Cowan founded Quotient through the acquisition of Alba Bioscience in 2007. He has a broad range of healthcare industry experience gained through over 15 years of employment within industry and investment banking. Previously, Mr. Cowan served as the Chief Financial Officer of Inveresk Research Group, a global contract research organization that was acquired by Charles River Laboratories in 2004. Prior to joining Inveresk in 2001, Mr. Cowan was a senior executive within the Investment Banking department of Bear Stearns & Co., where he led the European biotechnology practice. Prior to Bear Stearns, Mr. Cowan was a senior executive within the Investment Banking department of Morgan Grenfell (acquired by Deutsche Bank in 1990). Mr. Cowan received a Bachelor of Business in accounting from Queensland University of Technology.

Jeremy Stackawitz, President

Jeremy Stackawitz joined us in March 2009 and serves as one of our two Presidents. Mr. Stackawitz has over 17 years of healthcare industry experience gained through various consulting and industry roles. From 2007 to 2009, Mr. Stackawitz was Worldwide Commercial Director for Immunoematology of Ortho Clinical Diagnostics, a Johnson & Johnson company. Prior to this senior role, Mr. Stackawitz held positions from 2006 to 2007 at Therakos, a biotechnology company, from 2004 to 2006 at Ortho Biotech, and from 2000 to 2003 at Purdue Pharma L.P. He also

held consulting positions at ISO Healthcare Group (now part of Monitor Group) from 1997 to 2000 and McKinsey & Company in 2003. Mr. Stackawitz received a B.S. in chemistry from Dartmouth College and an M.B.A. from The Wharton School at the University of Pennsylvania.

Edward Farrell, President

Edward Farrell joined us in February 2013 and serves as one of our two Presidents. Mr. Farrell has over 20 years of engineering and manufacturing experience gained through various industry roles with a particular emphasis on medical diagnostics. From March 2001 to February 2013, Mr. Farrell held several senior positions with Bayer Diagnostics, which was acquired by Siemens Healthcare Diagnostics in 2007. Starting in 2010, Mr. Farrell was Managing Director and Vice President of Manufacturing for a high volume immunoassay reagent manufacturing plant in the United Kingdom. From 2007 to 2010, Mr. Farrell was Managing Director and Vice

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President of Manufacturing for a facility in the United Kingdom that develops and manufactures point-of-care diagnostic instruments and consumables. From 2005 to 2007, he worked in the United States as Director of Distribution, Service and Repair and initially worked in 2001 as a Senior Manufacturing Manager in a large instrument manufacturing plant in Ireland. Prior to Bayer Diagnostics, Mr. Farrell worked at Ingersoll Rand as a Production Manager from 1999 to 2001, Intel as a Manufacturing Engineer and Supervisor from 1995 to 1999, and Barlo plc as a Project Engineer from 1993 to 1995. Mr. Farrell received a B.E (Mechanical) and a Masters in Engineering Science from University College Dublin.

Stephen Unger, Chief Financial Officer

Stephen Unger joined us in January 2014 and serves as our Chief Financial Officer. Mr. Unger has over 20 years of financial and health care industry experience gained through various roles in investment banking and public accounting. Mr. Unger was a consultant to us on financial and strategic matters from April 2013 to December 2013. From 2009 to 2012, Mr. Unger was a Senior Equity Research Analyst following the medical diagnostics industry at Lazard Capital Markets, LLC, and worked from 1998 to 2008 in the Equity Research Department of Bear, Stearns & Co., where he was ultimately promoted to the position of Managing Director/Principal. He was also a Senior Accountant in the Audit Department of Deloitte & Touche LLP from 1993 to 1996. Mr. Unger is Certified Public Accountant (Inactive) and a Chartered Financial Analyst. He received a B.B.A. in accounting, finance, investment, and banking from the University of Wisconsin-Madison and an M.B.A. with Honors from The University of Chicago Booth School of Business.

Roland Boyd, Group Financial Controller and Treasurer

Roland Boyd joined us in August 2012 and serves as our Group Financial Controller and Treasurer. Mr. Boyd has over 35 years of financial experience gained through various roles in industry and public accounting. From 2006 to 2012, Mr. Boyd served as the Chief Financial Officer at Chiltern International Group, a global contract research organization. From 2002 to 2004, Mr. Boyd was Group Financial Controller at Inveresk Research Group and was a consultant to Charles River Laboratories until 2006 following Charles River's 2004 acquisition of Inveresk. Prior to that, Mr. Boyd spent over 20 years with Arthur Andersen, becoming a Partner in 1997. Mr. Boyd is a Fellow of the Institute of Chartered Accountants in England & Wales. Mr. Boyd received a B.A. (Hons) in accounting and finance from Lancaster University.

Employees

As of March 31, 2016, we had 331 employees. None of our employees are represented by a labor union or covered under a collective bargaining agreement, nor have we experienced any work stoppages. We believe our employee relations are good.

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.quotientbd.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

Quotient Limited is a limited liability no par value company incorporated under the laws of Jersey, Channel Islands. Our registered address is Elizabeth House, 9 Castle Street, St Helier, JE2 3RT, Jersey, Channel Islands. Our agent for service of process is our wholly owned U.S. subsidiary, Quotient Biodiagnostics, Inc., 301 South State Street, Suite S-204, Newtown, Pennsylvania 18940. We were incorporated in Jersey, Channel Islands in 2012. Our principal executive offices are located at Pentlands Science Park, Bush Loan, Penicuik, Midlothian, EH26 OPZ, United Kingdom, and our telephone number is 011-44-131-445-6159. Our website address is www.quotientbd.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, Industry and Future Plans

You should consider our business and prospects in light of the risks and difficulties we expect to encounter in the markets in which we compete, and the prospects of our development projects, particularly MosaiQ™. Factors that may contribute to fluctuations in our operating results include many of the risks described in this section. These fluctuations may make financial planning and forecasting difficult. In addition, these fluctuations may result in unanticipated decreases in our available cash, which could negatively affect our business and prospects. You should not rely on our operating results for any prior periods as an indication of our future operating performance.

We have incurred losses since our commencement of operations and expect to incur losses in the future.

We have incurred net losses and negative cash flows from operations in each year since we commenced operations in 2007. As of March 31, 2016, we had an accumulated deficit of \$108.2 million. We expect our operating losses to continue for at least the next fiscal year as we continue our investment in the development and commercialization of MosaiQ™. Because of the numerous risks and uncertainties associated with developing and commercializing MosaiQ™ and the other products we may develop, we are unable to predict the magnitude of any future operating 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. Our ability to achieve or sustain profitability is based on numerous factors, many of which are beyond our control, including market acceptance of our products, future product development, and our market penetration and margins.

We may need to raise additional capital, which may not be available on favorable terms, if at all, and which may cause dilution to shareholders, restrict our operations or adversely affect our ability to operate our business.

We expect to fund our operations in the near-term, including the continued development of MosaiQ™ to commercialization, from a combination of funding sources, including through the use of existing cash balances, asset-based financing, the achievement of product development milestones or the issuance of new equity or debt. We cannot be certain that we will be able to obtain additional financing on favorable terms, if at all, and any additional financings could result in additional dilution to our then existing shareholders or restrict our operations or adversely affect our ability to operate our business. If we are unable to obtain needed financing on acceptable terms, or otherwise, we may not be able to implement our business plan, which could have a material adverse effect on our business, financial condition and results of operations. We may not be able to meet our business objectives, our share price may fall and investors may lose some or all of their investment. If we raise funds by issuing equity securities, or if our outstanding options or warrants are exercised, the percentage ownership of our then shareholders will be reduced.

If we do not achieve, sustain or successfully manage our anticipated growth, our business and prospects will be harmed.

If we are unable to maintain adequate revenue growth, our financial results could suffer. Furthermore, significant growth will place strains on our management and our operational and financial systems and processes. If we do not successfully forecast the timing of regulatory authorization for product marketing and subsequent demand for our products or manage our anticipated expenses accordingly, our operating results will be harmed.

The development of MosaiQ™ includes many factors, including factors beyond our control, and we may not commercialize it on a timely basis, or at all.

Our future revenue growth and profitability will substantially depend on our ability to successfully commercialize MosaiQ™. We will need to complete development and obtain marketing authorizations from the FDA and other

regulatory authorities before we can commercialize MosaiQ™. Our ability to successfully commercialize MosaiQ™ may be affected by the following factors, among others:

- the scope of and progress made in our development activities;
- our ability to successfully complete field trial studies;
- our ability to obtain and maintain FDA and other regulatory authorizations;
- threats posed by competing technologies;
- our, or Ortho's or any other commercial partner's, ability to market MosaiQ to donor collection agencies, hospitals and independent testing laboratories;
- our ability to successfully optimize the individual tests to be included on both the blood grouping and disease screening consumables;

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the occurrence of unforeseen technical difficulties in the design and build of the manufacturing system for the consumables;
the occurrence of unforeseen technical difficulties in the design and manufacturing of the initial high-throughput instrument;
the occurrence of unforeseen technical difficulties in the development of software and the integration of the consumables, the instrument and software;
delays resulting from the failure of third-party suppliers or contractors to meet their obligations in a timely and cost-effective manner; and
endorsement and acceptance by donor collection agencies, hospitals and independent testing laboratories.

Development and commercialization of novel products, such as MosaiQ™, is inherently uncertain. At any point, we may abandon development of MosaiQ™ or we may be required to expend considerable resources addressing unforeseen technical challenges or otherwise to complete and commercialize MosaiQ™, which would adversely impact potential revenue and our expenses. In addition, any delay in product development would provide others with additional time to commercialize competing products before we introduce MosaiQ™, which in turn may adversely affect our growth prospects and operating results. Although we believe that our cost estimates and our project completion and commercialization schedule for MosaiQ™ are reasonable, we cannot assure you that the actual costs or time required to complete the project will not substantially exceed our current estimates.

Obtaining regulatory authorization for MosaiQ™ will take time, require material expenditures and ultimately may not succeed.

MosaiQ™ will be subject to CE-marking in Europe. In the United States, the FDA has indicated that it will require MosaiQ™ to obtain approval of a biologics license application, or BLA, for the blood grouping consumable and traditional 510(k) clearances for the instrument and the initial serological disease screening consumable, comprising two tests, CMV and syphilis. The final serological disease screening consumable, comprising additional tests, will be subject to BLA approval. The process of complying with the requirements of the FDA and comparable agencies is generally costly, time consuming and burdensome, and regulatory authorization is never guaranteed, irrespective of time and financial expenditures. Furthermore, given the complexities of the regulatory pathway for MosaiQ™, there may be delays in obtaining marketing authorization, or we may not be able to obtain marketing authorization at all. Moreover, the manufacturing process of the MosaiQ™ consumables is based on novel technologies and the FDA and regulatory agencies in other jurisdictions may have limited experience reviewing product candidates using these technologies, which may also result in delays in obtaining regulatory authorization for MosaiQ™.

Among other things, our manufacturing facility will be subject to pre-approval inspection by the FDA and other applicable regulators. In addition, we are required to perform field trial studies to obtain regulatory authorizations for MosaiQ™. Field trial studies are subject to factors within and outside of our control and the outcome of these studies is uncertain. For example, success in early feasibility studies may not be replicated in later field trial studies. Although our internal blood grouping feasibility studies have demonstrated a high degree of concordance, across a range of key specificities, between results generated by the MosaiQ™ methodology and results using predicate technologies for antigen typing and antibody identification, and although our initial feasibility work on the disease screening consumable has been positive, there is no guarantee that our analytical testing will meet the FDA's or other regulatory authorities' requirements, that our field trial studies will be successful, that the FDA or other regulatory authorities will provide marketing authorization for MosaiQ™ based on the studies we have completed or, if we obtain market authorization, that the prognostic information that may be reported will differentiate MosaiQ™ from alternatives in the United States or other markets. Even if our field trials are successful and we obtain the necessary regulatory authorizations, the regulatory review process will still take time and require material expenditures.

Our substantial reliance on third parties to develop MosaiQ™ exposes us to a number of risks that may delay the development and commercialization of MosaiQ™ or result in higher costs to us.

We have outsourced certain elements of the development of MosaiQ™. Our dependence on third parties for the development of our manufacturing system for consumables and our initial high-throughput instrument may subject us to a number of risks. For example, our third-party developers may not be able to develop or manufacture components of the MosaiQ™ system, or may apply insufficient resources to the development of MosaiQ™ in the manner required to meet our technical and commercial requirements, on our expected timetable or within our expected cost estimates. If our existing third-party developers are unable, or fail, to meet our requirements, there can be no assurance that we will be able to enter into relationships with other third parties necessary to successfully develop MosaiQ™. Any of these risks could materially harm our business and adversely affect our future revenues.

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MosaiQ™ consumables have not been manufactured on a commercial scale and are subject to unforeseen scale-up risks.

While we have developed the manufacturing system for MosaiQ™ consumables, there can be no assurance that we can manufacture MosaiQ™ consumables at a scale that is adequate for our commercial needs. We may face significant or unforeseen difficulties in manufacturing the MosaiQ™ consumables, including but not limited to:

- technical issues relating to manufacturing products on a commercial scale at reasonable cost, and in a reasonable time frame;
- difficulty meeting demand or timing requirements for consumable orders due to excessive costs or lack of capacity for part or all of an operation or process;
- lack of skilled labor or unexpected increases in labor costs needed to produce or maintain our manufacturing systems or perform certain required operations;
- changes in government regulations or in quality or other requirements that lead to additional manufacturing costs or an inability to supply product in a timely manner, if at all; and
- increases in raw material or component supply cost or an inability to obtain supplies of certain critical supplies needed to complete our manufacturing processes.

These and other difficulties may only become apparent when scaling up the manufacturing of the MosaiQ™ consumables to more substantive commercial scale. In the event our MosaiQ™ consumables cannot be manufactured in sufficient commercial quantities, our future prospects could be significantly impacted and our financial prospects would be materially harmed.

We expect to rely on third parties to conduct studies of MosaiQ™ and our other transfusion diagnostics products that will be required by the FDA or other regulatory authorities and those third parties may not perform satisfactorily.

We do not have the ability to independently conduct the field trial studies or other studies that may be required to obtain FDA and other regulatory clearances or approvals for MosaiQ™ as well as our conventional reagent products. Accordingly, we expect to rely on third parties, such as independent testing laboratories and hospitals, to conduct such studies. Our reliance on these third parties will reduce our control over these activities. These third-party contractors may not complete activities on schedule or conduct studies in accordance with regulatory requirements or our study design. We cannot control whether they devote sufficient time, skill and resources to our studies. Our reliance on third parties that we do not control will not relieve us of any applicable requirement to prepare, and ensure compliance with, various procedures required under good clinical practices. If these third parties do not successfully carry out their contractual duties or regulatory obligations or meet expected deadlines, if the third parties need to be replaced or if the quality or accuracy of the data they obtain is compromised due to their failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our studies may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for MosaiQ™ or our other transfusion diagnostic products.

Our commercial success will largely depend upon the degree of market acceptance of MosaiQ™ by donor collection agencies, hospitals and independent testing laboratories.

MosaiQ™ may not gain sufficient market acceptance by donor collection agencies, hospitals and independent testing laboratories. If the product does not achieve an adequate level of acceptance by these critical customer groups, our future revenue growth and profitability would be materially impacted. The degree of market acceptance of MosaiQ™ will depend on a number of factors, including:

- the efficacy and potential advantages of MosaiQ™ over alternative technologies, techniques and products, including both conventional technologies such as existing testing methods from Ortho, Immucor, Bio-Rad, Grifols and Beckman Coulter, as well as new technologies from such companies or new competitors;
- limitations contained in the approved labeling for MosaiQ™;
- the willingness of our target customers to transition from existing technologies, products and procedures and to adopt MosaiQ™;

the ability to offer attractive pricing for MosaiQ™;

the strength of marketing and distribution support and the timing of market introduction of competitive products; and outcomes from field trial studies, the regulatory approval process, and other publicity concerning MosaiQ™ or competing products.

Our efforts to educate donor collection agencies, hospitals, independent testing laboratories and other members of the medical community on the benefits of MosaiQ™ may require significant resources and may never be successful. Such efforts to educate the

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marketplace may require more resources than are required by conventional or new technologies marketed by our competitors. If we were to incorrectly forecast our ability to penetrate various 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 MosaiQ™ is the subject of industry or clinical guidelines, field trial studies or scientific publications that are unhelpful or damaging, or otherwise call into question the benefits of MosaiQ™, we may have difficulty convincing prospective customers to adopt MosaiQ™.

Our commercialization plan for MosaiQ™ in the patient testing market depends on our distribution and supply agreement with Ortho.

We will rely on Ortho to commercialize MosaiQ™ in the highly fragmented patient testing market. Under our distribution and supply agreement, Ortho has agreed to commercialize MosaiQ™ in the global patient testing market, as well as certain territories in the donor testing market. Ortho may not commit sufficient resources to this commercialization arrangement, as MosaiQ™ may compete for time, attention and resources with Ortho's internal programs, or Ortho otherwise may not perform its obligations as expected. In addition, Ortho is both a customer and a competitor of our conventional reagent business. If Ortho is unable, or fails, to perform its obligations, there can be no assurance that we will be able to enter into commercialization relationships with other partners with sufficient existing global sales and support infrastructures necessary to successfully commercialize MosaiQ™ in the patient testing market. Any of these risks could delay the commercialization of MosaiQ™ in the patient testing market, result in high costs to us or otherwise materially harm our business and adversely affect our future revenues.

Other companies or institutions may develop and market novel or improved methods for transfusion diagnostics, which may make MosaiQ™ less competitive or obsolete.

The market for transfusion diagnostics is large and established, and our competitors may possess significantly greater financial resources and have larger development and commercialization capabilities than we do. Although we are not aware of any companies that are pursuing an alternative fully automated blood grouping and disease screening platform like MosaiQ™, a platform or technology that competes with MosaiQ™ may be developed. We may be unable to compete effectively against these competitors either because their diagnostic platforms are superior or because they may have more expertise, experience, financial resources or stronger business relationships.

We have leased a factory in Eysins, Switzerland, which will become the principal manufacturing site for the MosaiQ™ consumables, and any delay in obtaining regulatory approval may delay or prevent the launch of MosaiQ™.

We have leased a manufacturing facility in Eysins, Switzerland, which will become the principal manufacturing site for the MosaiQ™ consumables. The validation of the MosaiQ™ manufacturing system is subject to many risks, including the fact that, in connection with products that will be sold in the United States, this new facility will be subject to a pre-approval inspection by the FDA, and, in connection with products sold outside the United States, this new facility will be subject to pre-approval inspection by applicable foreign regulators, which could prevent or delay the launch of MosaiQ™.

Our near-term success is dependent upon our ability to expand our customer base and introduce new conventional reagent products.

Our current customer base is primarily composed of donor testing laboratories and hospitals that use our conventional reagent products for blood grouping, along with original equipment manufacturers, or OEMs (for example, Ortho, Bio-Rad and Grifols). Our success will depend, in part, upon our ability to expand our customer base and increase our market penetration of existing customers through the development and commercialization of new products after obtaining regulatory authorization. Attracting new customers and introducing new products requires substantial time and expense. Any failure to expand our existing customer base, or launch new products, would adversely affect our operating results.

Our financial performance depends in part upon our ability to successfully develop and market new products in a rapidly changing technological and economic environment. If we fail to successfully introduce new conventional reagent products, we could lose market share. We could also lose market share if our competitors introduce new products or technologies that render our conventional reagent products less competitive or obsolete. In addition, delays in the introduction of new products due to regulatory, developmental or other obstacles could negatively impact our revenue and market share, as well as our earnings.

We are dependent upon our three largest OEM clients for a substantial portion of our total revenues. If any of our key OEM customers terminates or reduces the scope of its relationship with us, our product sales will suffer.

We develop, manufacture and sell a range of our conventional reagent products to customers who are major OEMs. These products are sold in bulk, for inclusion in products manufactured by these OEM customers, or as finished, vialled products. Product sales to our three largest OEM customers accounted for 67% of our total revenues and product sales to Ortho accounted for 57% of our total

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revenues in the year ended March 31, 2016. If any of our OEM customer agreements are terminated, particularly our agreement with Ortho, or the scope of our OEM customer relationships is otherwise reduced, our product sales could decrease, and our results of operations may be negatively impacted. In particular, a change of control of any of our OEM customers could negatively impact our relationship. Further, we may not be able to enter into new customer agreements on satisfactory terms, or at all.

Our OEM customers, including Ortho, are also our competitors. Our business may be harmed if, as a result of the commercialization of MosaiQ™, Ortho or our other OEM customers perceive MosaiQ™ as a competitive product, resulting in a discontinuation of Ortho's or our other OEM customers' purchases from us.

Gross margin volatility may negatively impact our profitability.

Our gross margin has been volatile from period to period in the past and may be volatile in the future due to various factors, including changes in product mix, shipment cycles and manufacturing costs. Gross margins on our conventional reagent products vary depending upon the product, with whole blood control products, rare antibodies and red blood cell-derived products generating higher margins. Depending upon the sales mix of these products, our gross margin could vary significantly from period to period. Our conventional reagent products are manufactured by us. As such, gross margins for these products could be impacted by a rise in the costs of raw materials and labor, as well as overhead and the efficiency of our manufacturing operations. Our gross margin may also be negatively impacted by increased competition. Specifically, suppliers in the market seeking to maintain or grow market share may foster a competitive environment of pricing pressures that could negatively impact the profitability of product sales.

If we are unable to maintain our network of direct sales representatives, we may not be able to generate anticipated sales of our current or future products.

We expect our direct sales representatives to develop long-lasting relationships with the customers they serve. If our direct sales representatives fail to adequately promote, market and sell our conventional reagent products, our sales could significantly decrease. If a substantial number of our direct sales representatives were to leave us within a short period of time, our sales could be adversely affected. If a direct sales representative 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. We may be unable 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 would prevent us from expanding our business and generating sales.

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 manufacturing of our conventional reagent products that could 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 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 products, reduce our product gross margin and adversely impact our business. If we are unable to keep up with demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue could be impaired, market acceptance for our products 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.

Demand for our products depends in part on the operating budgets of our customers and their spending levels, a reduction in which could limit demand for our products and adversely affect our business.

In the near term, we expect that our revenue will be derived primarily from sales of our conventional reagent products to hospitals and independent testing laboratories for blood grouping, either directly or through our OEM customers.

The demand for our products will depend in part upon the operational budgets of these customers, which are impacted by factors beyond our control, such as:

- global macroeconomic conditions;
- changes in the regulatory environment;
- differences in budgetary cycles;
- market-driven pressures to consolidate operations and reduce costs; and
- market acceptance of new technologies.

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Our operating results may fluctuate due to reductions and delays in expenditures by our customers. Any decrease in our customers' budgets or expenditures, or in the size, scope or frequency of operating expenditures, could materially and adversely affect our business, operating results and financial condition.

The transfusion diagnostics market is highly competitive. If we fail to compete effectively, our business and operating results will suffer.

We face significant competition in the transfusion diagnostics market. We currently compete with established diagnostic companies that design, manufacture and market instruments and consumables for blood grouping. We believe our principal competitors in the transfusion diagnostics market are Ortho, Immucor and Bio-Rad.

Most of our current competitors have greater financial resources than we do, making them better equipped to fund research and development, manufacturing and marketing efforts or license technologies and intellectual property from third parties. Our competitors can be expected to continue to improve the performance of their products and to introduce new products with competitive price and performance characteristics. Although we believe we have advantages over our competitors, maintaining these advantages will require us to continue to invest in research and development, sales and marketing and customer service and support.

Our current competitors are either privately owned, publicly-traded companies or are divisions of publicly-traded companies, and enjoy a number of competitive advantages over us, including:

- greater name and brand recognition, financial and human resources;
- broader product lines;
- larger sales forces and more established distributor networks;
- substantial intellectual property portfolios;
- larger and more established customer bases and relationships; and
- better established, larger scale, and lower cost manufacturing capabilities.

We believe that the principal competitive factors in all of our target markets include:

- cost of capital equipment;
- cost of consumables and supplies;
- reputation among customers;
- innovation in product offerings;
- flexibility and ease-of-use;
- accuracy and reproducibility of results;
- compatibility with existing laboratory processes, tools and methods;
- breadth of clinical decisions that can be influenced by information generated by tests; and
- economic benefit accrued to customers based on testing services enabled by products.

We cannot assure investors that we will be successful in the face of competition from new products and technologies introduced by our existing competitors or new companies entering our markets. In addition, we cannot assure investors that our competitors do not have or will not develop products or technologies that currently or in the future will enable them to produce competitive products with greater capabilities or at lower costs than ours.

New technologies, techniques or products could emerge that might offer better combinations of price and performance than our current or future products and systems.

It is critical to our success that we anticipate changes in technology and customer requirements and to successfully introduce, on a timely and cost-effective basis, new, enhanced and competitive technologies that meet the needs of current and prospective customers. If we do not successfully innovate and introduce new technology into our product lines or manage the transitions to new product offerings, our revenues, results of operations and business will be adversely impacted. Competitors may be able to respond more quickly and effectively than we can to new or changing

opportunities, technologies, standards or customer requirements. We anticipate that we will face increased competition in the future as existing companies and competitors develop new or improved products and as new companies enter the market with new technologies.

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We are dependent on single source suppliers for some of the components and materials used in our conventional reagent products, and supply chain interruptions could negatively impact our operations and financial performance.

Our products are manufactured by us and we obtain supplies from a limited number of suppliers. In some cases, critical components required to manufacture our products may only be available from a sole supplier or limited number of suppliers, any of whom would be difficult to replace. The supply of any of our manufacturing materials may be interrupted because of poor vendor performance or other events outside our control, which may require us, among other things, to identify alternate vendors and result in lost sales and increased expenses. Even if the manufacturing materials that we source are available from other parties, the time and effort involved in validating the new supplies and obtaining any necessary regulatory approvals for substitutes could impede our ability to replace such components in a timely manner or at all.

In particular, some of our conventional reagent products are derived from blood having particular or rare combinations of antibodies or antigens, which are found in a limited number of individuals. If we had difficulty in obtaining sufficient quantities of such blood, we would need to establish a viable alternative, which may take both time and expense to either identify and/or develop.

The loss of a sole 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.

If our Edinburgh, Scotland facility becomes unavailable or inoperable, we will be unable to produce and ship many of our conventional reagent products.

All our conventional reagent products are produced in our Edinburgh, Scotland manufacturing facility. While we believe we have reliable suppliers of raw materials, our reagent production is highly dependent on the uninterrupted and efficient operation of the Edinburgh, Scotland facility and we currently have no alternative manufacturing capabilities. Therefore, if a catastrophic event occurred at the Edinburgh, Scotland facility, such as a fire or contamination, many of our products could not be produced until the manufacturing portion of the facility was restored and cleared by the FDA. We maintain a disaster plan to minimize the effects of such a catastrophe and we have obtained insurance to protect against certain business interruption losses (we have £24 million of coverage for our Edinburgh manufacturing facility and an additional £1 million of coverage for our research and development activities). However, there can be no assurance that such coverage will be adequate or that such coverage will continue to remain available on acceptable terms, if at all.

Our customers, including our U.S. commercial operations, receive all of their conventional reagent products from our Edinburgh, Scotland manufacturing facility. If circumstances arose that disrupted our international distribution of products from Edinburgh, we would need to establish an alternate distribution channel, which may take both time and expense to establish.

The landlord for our Edinburgh, Scotland manufacturing operation is Scottish National Blood Transfusion Service, or SNBTS. The lease on our Edinburgh, Scotland facility ends in August 2016. We have commenced discussions with SNBTS to extend this lease to allow us to complete the build of a new manufacturing facility near Edinburgh, Scotland. There can be no assurance that SNBTS will extend the existing lease on acceptable terms or terms equivalent to those we currently have.

We are building a new, expanded manufacturing facility for our conventional reagent products, which may result in overlapping operations and duplicative costs, impair manufacturing operations, delay or prevent the launch of new products or require us to expend additional capital.

To meet expected future demand for our conventional reagent products, we are building a new expanded manufacturing facility in Edinburgh, Scotland near our existing manufacturing facility. Our failure to complete the new facility on time and on budget may result in the need for us to raise additional capital and may impair the efficient operation of our manufacturing system. In addition, moving our manufacturing operations to a new facility may result in overlapping operations and duplicative costs during the transition period. Furthermore, changes in our manufacturing process or procedure, including a change in the location where our products are manufactured, will require prior FDA review and approval of the manufacturing process and procedures. Any new facility will be subject to a pre-approval inspection by the FDA and would again require us to demonstrate product comparability to the FDA. There are comparable foreign requirements as well. This review may be costly and time consuming and could delay or prevent the launch of any new product.

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We generate a substantial portion of our revenue internationally and are subject to various risks relating to our international activities.

A significant proportion of our revenues are earned in U.S. Dollars but the costs of our manufacturing operations are payable mainly in Pounds Sterling. As a result, fluctuations in foreign currency exchange rates against the U.S. Dollar could impact our financial results adversely. We believe a significant percentage of our future revenue and costs will come from international sources.

Engaging in international business also involves a number of difficulties and risks, including:

- required compliance with existing and changing foreign regulatory requirements and laws;
- required compliance with anti-bribery laws, such as the U.S. Foreign Corrupt Practices Act and UK Bribery Act, data privacy requirements, labor laws and anti-competition regulations;
- export or import restrictions;
- various reimbursement and insurance regimes;
- laws and business practices favoring local companies;
- longer payment cycles and difficulties in enforcing agreements and collecting receivables through certain foreign legal systems;
- political and economic instability;
- potentially adverse tax consequences, tariffs, customs charges, bureaucratic requirements and other trade barriers;
- difficulties and costs of staffing and managing foreign operations; and
- difficulties protecting or procuring intellectual property rights.

The occurrence of any of these factors in the countries in which we operate could materially adversely affect our business, results of operations and financial condition.

Our debt and other financings contain restrictive and financial covenants and other provisions that may limit our operating flexibility.

Our \$30 million term loan agreement (“MidCap Facility”) with MidCap Financial Trust (“MidCap”), as administrative agent, contains certain restrictive covenants that limit our ability to merge with other companies or consummate certain changes of control, acquire other companies, engage in new lines of business, make certain investments, pay dividends, transfer or dispose of assets, amend certain material agreements or enter into various specified transactions. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the lender or terminate the term loan agreement. The loan agreement also contains certain financial covenants, including minimum revenue requirements and a covenant to maintain cash balances in excess of \$10 million, and is secured by all of our assets. There is no guarantee that we will be able to generate sufficient cash flow or sales to meet the financial covenants or pay the principal and interest under the agreement. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repay or refinance the amounts outstanding under the agreement.

In addition, our outstanding 666,665 7% cumulative redeemable preference shares are subject to automatic redemption in the event of certain changes of control involving us. In connection with such redemption, we are required to first pay the amount of the accrued and unpaid preferential dividend on the preference shares and then redeem the preference shares at a redemption price of \$22.50 per preference share. There is no guarantee that we will have sufficient funds legally available to make such redemption.

Undetected errors or defects in our products could expose us to product liability claims, harm our reputation or decrease market acceptance of our products.

The sale and use of products or services based on our technologies could lead to the filing of product liability claims if someone were to allege that one of our products contained a design or manufacturing defect, which resulted in the

failure to adequately perform the analysis for which it was designed. A product liability claim could result in substantial damages and be costly and time consuming to defend, either of which could materially harm our business or financial condition. We maintain insurance that includes product liability coverage of approximately \$7 million as of March 31, 2016 and we believe our insurance coverage is adequate for our business. However, there can be no assurance that insurance coverage for these risks will continue to be available or, if available, that it will be sufficient to cover potential claims or that the present level of coverage will continue to be available at a reasonable cost. Our existing insurance may have to be increased in the future if we are successful at introducing new transfusion diagnostics products and this will increase our costs. Under certain of our customer and license agreements, we have agreed to provide indemnification for

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product liability claims arising out of the use of our products. 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 products 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.

We may also be subject to warranty claims for damages related to errors or defects in our products. A material liability claim or other occurrence that harms our reputation or decreases market acceptance of our products could harm our business and operating results. In the event that we experience a product performance problem, we may be required to, or may voluntarily recall or suspend selling the products until the problem is resolved. Depending on the product as well as the availability of acceptable substitutes, such a product recall or suspension could significantly impact our operating results.

The outcome of any future disputes, claims and litigation could have a material adverse impact on our business, financial condition and results of operations.

We may, from time to time, be party to litigation in the normal course of business, including class action and product liability lawsuits. Due to the inherent uncertainties of litigation, it is not possible to predict the final outcome of these lawsuits or determine the amount of any potential losses we may incur. In the event we are required or determine to pay amounts in connection with any such lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations.

We are highly dependent on our senior management team and other key employees, and our success depends on our ability to retain our managerial personnel and to attract additional personnel.

Our success is dependent upon the efforts of our senior management and staff, including sales, technical and management personnel, many of whom have very specialized industry and technical expertise that is not easily replaced. In particular, our success depends in part upon the continued service of our Chairman and Chief Executive Officer, Paul Cowan, who is critical to the overall management of our company. This includes the shaping of our culture and our strategic direction. If key individuals leave us, we could be adversely affected if suitable replacement personnel are not quickly recruited. We have entered into employment agreements with our executive officers and senior managers, including our Chairman and Chief Executive Officer, but none of these agreements guarantees the service of the individual for a specified period of time. Our future success depends on our ability to continue to attract, retain and motivate qualified personnel. There is intense competition for medical technologists and in some markets there is a shortage of qualified personnel in our industry. If we are unable to continue to attract or retain highly qualified personnel, the development, growth and future success of our business could be adversely affected.

We may 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 us.

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:

- problems assimilating the purchased 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;

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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.

We have no current commitments with respect to any acquisition or investment. Any acquisitions we undertake 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 acquired businesses, products or technologies effectively, our business, results of operations and financial condition may be materially adversely affected.

We may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships to develop proposed products and to pursue new markets. Proposing, negotiating and implementing collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. Other companies, including those with substantially greater financial, marketing, sales, technology or other business resources, may compete with us for these opportunities or arrangements. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products.

Additionally, we may not be in a position to exercise sole decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. For example, our distribution and supply agreement with Ortho provides for a six-person steering committee composed of three of our representatives and three of Ortho's representatives, which provides liaison, coordination and strategic planning with regard to development and regulatory approval of MosaiQ™ and the sale and distribution of MosaiQ™ instruments and consumables by Ortho. It is possible that conflicts may arise with our collaborators, such as conflicts concerning the achievement of performance milestones, or the interpretation of significant terms under any agreement, such as those related to financial obligations or the ownership or control of intellectual property developed during the collaboration. If any conflicts arise with our current or future collaborators, they may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. In addition, we have limited control over the amount and timing of resources that our current collaborators or any future collaborators devote to our collaborators' or our future products. Disputes between us and our collaborators may result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements and, in such event, we may not continue to have rights to the products relating to such transaction or arrangement or may need to purchase such rights at a premium.

Risks Related to Government Regulation

If we, Ortho or our other commercial partners fail to comply with extensive foreign and domestic regulations, sales of our products in new and existing markets and the development and commercialization of any new product candidates, including MosaiQ™, could be delayed or prevented.

Our reagents and other products are subject to regulation by governmental and private agencies in the United States and abroad, which, among other things, regulate the testing, manufacturing, packaging, labeling, distribution,

promotion, marketing, import and export of medical supplies and devices. Certain international regulatory bodies also impose import and tax restrictions, tariff regulations, and duties on imported products. Delays in agency review can significantly delay new product introduction and may result in a product becoming “outdated” or losing its market opportunity before it can be introduced.

Also, the FDA and international agencies have the authority to require a recall or modification of products in the event of a defect or to prohibit or limit the distribution or importation of the product.

FDA approval of a BLA or clearance of a 510(k) generally is required before we can market new reagents in the United States or make significant changes to existing products. The process of obtaining licenses, marketing clearances and approvals from regulatory agencies can be time consuming and expensive. There is no assurance that marketing authorizations will be granted or that agency reviews will not involve delays that would adversely affect our ability to commercialize our products, including MosaiQ™.

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If any of our products were to fail to perform in the manner represented during review of the product application, particularly concerning clinical performance, one or more of these agencies could place restrictions on the labeling, marketing, distribution or use of the product, require us to cease manufacturing and selling that product, or even recall previously-placed products, and, if the product must be modified in order to resolve the problem, to resubmit the product for market authorization before we could sell it again. Depending upon the product, and the availability of acceptable substitutes, such an agency action could result in significantly reduced revenues and earnings for an indefinite period.

Federal, state and foreign regulations regarding the manufacture and sale of our products are subject to change. We cannot predict what impact, if any, such changes might have on our business. In addition, there can be no assurance that regulation of our products will not become more restrictive in the future and that any such development would not have a material adverse effect on our business.

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 or clearance in the United States or in international jurisdictions, along with the manufacturing processes 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. Our failure or the failure of one of our suppliers to comply with statutes and regulations administered by the FDA and other regulatory bodies, or our failure to take adequate action in response to any observations, could result in, among other things, any of the following enforcement actions, any one of which could harm our reputation and could cause our product sales and profitability to suffer:

- finances and civil penalties;
- the requirement to take corrective actions;
- delays in approving or clearing, or refusal to approve or clear, our products;
- withdrawal or suspension of approval or clearances by the FDA or other regulatory bodies;
- product recall or seizures;
- interruption of production;
- restrictions on labeling, marketing, distribution or use of our products;
- an import or export ban on our products;
- injunctions; and
- criminal prosecution.

We may also receive warning letters or untitled letters regarding compliance with current good manufacturing practices at our Edinburgh facility, but we have not received any such warning letters or untitled letters since 2009.

Any regulatory approval or clearance 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 may 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, manufacturing problems or failure to comply with regulatory requirements may result in restrictions on such products or manufacturing processes. Other potential consequences include revisions to the approved labeling, 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 transfusion diagnostics 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 warning or untitled letters, fines, product recalls, field actions, product seizures or, in extreme cases, criminal sanctions.

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Additionally, healthcare policy has been a subject of extensive discussion in the executive and legislative branches of the federal and many state governments and healthcare laws and regulations are subject to change. Our reagent product business strategy, and the development of the commercialization strategy for MosaiQ™, have been based on existing healthcare policies. We cannot predict what additional changes, if any, will be proposed or adopted or the effect that such proposals or adoption may have on our business, financial condition and results of operations.

Approval and/or clearance by the FDA and foreign regulatory authorities for our transfusion diagnostics products could take significant time and require significant development expenditures.

Obtaining FDA and other regulatory clearances or approvals for MosaiQ™ and our newly developed conventional reagent products can be expensive and uncertain. It can take from several months to several years from the date of submission of the application, and generally requires detailed and comprehensive scientific and clinical data. As with all blood transfusion products, the FDA and other regulatory authorities reserve the right to redefine the regulatory path at the time of submission or during the review process, and could require a more burdensome approach than we currently anticipate. Notwithstanding the time and expense, these efforts may never result in FDA approval or clearance or that of other regulatory authorities. Even if we were to obtain regulatory approval or clearance, it may not be for the uses we believe are important or commercially attractive, in which case we would not be permitted to market our product for those uses.

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

The handling of materials used in the manufacture of transfusion diagnostics products involves the controlled use of biological and hazardous materials and wastes. The primary hazardous materials we handle or use include human blood donations. 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 relationships with customers are subject to applicable anti-kickback, fraud and abuse and other domestic healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians at hospitals and public health departments play a primary role in the recommendation and ordering of our reagents and other products, and may play an important role in the recommendation and ordering of the MosaiQ™ system. Our arrangements with customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product.

The 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 federal 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 material to a false or fraudulent action or improperly avoiding, decreasing or concealing 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. In addition, HIPAA created 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.

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The federal Physician Payment Sunshine Act requirements under the PPACA (as defined below) 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 federal False Claims Act, with potential liability including mandatory treble damages and significant per-claim penalties, currently set at \$5,500 to \$11,000 per false claim. Additionally, it is possible that governmental authorities will conclude that our business practices may 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 UK 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 UK 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, Ortho and our other 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, 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 and Trade Control laws. If we are not in compliance with the Bribery Act, the FCPA and 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 of any potential violations of the Bribery Act, the FCPA, other anti-corruption laws or Trade Control laws by UK, U.S. or other authorities could also have an adverse impact on our reputation, our business, results of operations and financial condition.

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

Changes in government policy could have a significant impact on our business by increasing the cost of doing business, affecting our ability to sell our products and negatively impacting our profitability. Such changes could include modifications to existing legislation, such as U.S. tax policy, or entirely new legislation, such as the Patient Protection and Affordable Care Act (PPACA) that became law in March 2010. The PPACA makes changes that are expected to significantly impact the pharmaceutical and medical device industries and clinical laboratories. Elements of this legislation could meaningfully change the way healthcare services are delivered and may materially impact aspects of our business. We cannot predict whether future healthcare initiatives will be implemented at the federal or

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state level or in countries outside of the United States in which we may do business, or the effect any future legislation or regulation will have on us.

Risks Related to Intellectual Property

The extent to which we can protect our products and technologies through intellectual property rights that we own, acquire or license is uncertain.

We employ a variety of proprietary and patented technologies and methods in connection with the products we sell or are developing, including MosaiQ™. We license some of these technologies from third parties. We cannot provide any assurance that the intellectual property rights that we own or license provide effective protection from competitive threats or that we would prevail in any litigation in which our intellectual property rights are challenged. In addition, we cannot provide any assurances that we will be successful in obtaining new proprietary or patented technologies or methods in the future, whether through acquiring ownership or through licenses from third parties.

We cannot assure investors that any of our currently pending or future patent applications will result in issued patents, and we cannot predict how long it may take for a patent to issue on any of our pending patent applications, assuming a patent does issue. Further, we cannot assure investors that other parties will not challenge any patents issued or exclusively licensed to us or that courts or administrative agencies will hold our patents or the patents we license on an exclusive basis to be valid and enforceable. We cannot guarantee investors that we will be successful in defending challenges made against our patents and other intellectual property rights. Any third-party challenge to any of our patents could result in the unenforceability or invalidity of some or all of the claims of such patents and could be time consuming and expensive.

The extent to which the patent rights of life sciences companies effectively protect their products and technologies is often highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the proper scope of allowable claims of patents held by such companies has emerged to date in the United States. Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostics tests or 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 a law of nature itself. What constitutes a “sufficient” additional feature for this purpose 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 exclusively licensed patents.

We cannot predict the breadth of claims that may be allowed or enforced in patents we own or in those to which we have exclusive license rights. For example:

- the inventor(s) named in one or more of our patents or patent applications might not have been the first to have made the relevant invention;
- the inventor (or his assignee) might not have been the first to file a patent application for the claimed invention;
- others may independently develop similar or alternative products and technologies or may successfully replicate our product and technologies;
- it is possible that the patents we own or in which we have exclusive license rights may not provide us with any competitive advantages or may be challenged by third parties and found to be invalid or unenforceable;
- any patents we obtain or exclusively license may expire before, or within a limited time period after, the products and services relating to such patents are commercialized;
- we may not develop or acquire additional proprietary products and technologies that are patentable; and
- others may acquire patents that could be asserted against us in a manner that could have an adverse effect on our business.

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. 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. Patent applications in the United States and many foreign jurisdictions are not published until at least eighteen months after filing and it is possible for a patent application filed in the United States to be

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maintained in secrecy until a patent issues on the application. In addition, publications in the scientific literature often lag behind actual discoveries. We therefore cannot be certain that others have not filed patent applications that cover inventions that are the subject of pending applications that we own or exclusively 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 that is similar to or the same as our technology. Any such patent application may have priority over patent applications that we own or exclusively license and, if a patent issues on such patent application, we could be required to obtain a license to such patent in order to carry on our business. If another party has filed a U.S. patent application covering an invention this is similar to, or the same as, an invention 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 our inability to obtain or retain any U.S. patent rights with respect to such invention.

Some of our competitors may be better able to sustain the costs of complex patent disputes and litigation 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 and non-disclosure 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.”

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.

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 exclusively licensed intellectual property rights may not be sufficient to prevent others from manufacturing, using or selling competing products. For example, our manufacturing process for MosaiQ™ consumables depends in part on intellectual property that we in-license on an exclusive basis, and such rights may be limited. Our competitors may have obtained or be able to develop or obtain a license to similar intellectual property. 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 and thereby avoid infringing our intellectual property rights. If our intellectual property is not sufficient to effectively prevent our competitors from developing and selling similar products, our competitive position and our business could be adversely affected.

MosaiQ™ depends on certain technologies that are licensed to us. We do not control these technologies and any loss of our rights to them could prevent us from manufacturing our products.

We rely on licenses to various proprietary technologies that are material to our business, including the development of MosaiQ™. We have entered into an exclusive license with The Technology Partnership plc, or TTP, to patented technologies to enable high volume manufacturing of MosaiQ™ consumables. In addition, STRATEC Biomedical AG, or STRATEC, has agreed to grant us licenses to certain of its pre-existing technologies, and has granted us licenses to its technologies to be developed under our development agreement with it for the MosaiQ™ instrument. Our rights to use these technologies will be subject to the continuation of and our compliance with the terms of those licenses. If we were to lose access to these licenses, we would be unable to manufacture MosaiQ™ consumables or commercialize MosaiQ™ instruments until we obtained access to a comparable technology.

We may not control the prosecution, maintenance or filing of the patents to which we now hold or in the future intend to acquire licenses. Enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents may be 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 relevant licensors have been or will be conducted in compliance with

applicable laws and regulations, will result in valid and enforceable patents or that any patents or patents that may issue in the future on any patent applications owned by or exclusively licensed to us will provide any competitive advantage.

Certain of our licenses contain, and any future licenses may contain, provisions that allow the licensor to terminate the license upon the occurrence of certain events, such as material breach by us or our insolvency. For example, the licenses granted under the development agreement with STRATEC would be null and void upon termination of the development agreement by STRATEC. The TTP license is for uses that include antigen typing, antibody detection and serological screening of donated blood for infectious diseases (collectively, the initial purpose), as well as all human blood sample diagnostic testing on batch processing instruments (collectively, the additional purposes), with the exception of companion diagnostics, epigenetics, and nucleic acid sequencing. If any of certain agreed upon license payments are not made by us when due, we will lose the license to the additional purposes, but not the initial purpose. TTP may terminate its license agreement with us if we assist another party in disputing the validity and/or scope of any of TTP's patented intellectual property covered by the agreement. If the licensors of the technologies we rely on were to terminate our license agreements, the commercialization of MosaiQ™ could be prevented or delayed, and we may be unable to find a suitable replacement technology at an acceptable cost or at all. Our rights under each of the licenses may be subject to our continued compliance with the terms of the license, including certain diligence, disclosure and confidentiality obligations and the payment of fees. If we breach any of our license agreements and fail to cure the breach within any applicable cure period, our licensors may take action against us, including termination of the applicable license. Determining the scope of our licenses and related obligations can be difficult and could lead to disputes between us and the licensors. An unfavorable resolution of such a dispute could lead to termination of the license to which a dispute relates. If a licensor terminates a license agreement because of a breach by us that we fail to timely cure, we might no longer have the right to produce or sell some or all of our products and we may be subject to other liabilities, which could have a material adverse effect on our business.

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.

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, 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 re-examination) in the United States and internationally involve complex legal and factual questions. As a result, such proceedings are costly and time consuming to pursue, and their outcome is uncertain.

Even if we prevail in such a proceeding in which we assert our intellectual property rights against third parties, 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 exclusively license could also have an impact on our business. Further, if any of our other owned or exclusively licensed patents are declared invalid, unenforceable or narrowed in scope, our competitive position could be adversely affected.

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 damages or licensing fees and limit our ability to sell some or all of our products and services.

Our research, development and commercialization activities may infringe or be claimed to infringe patents or other intellectual property rights owned by other parties of which we may be unaware because the relevant patent applications may have been filed but not yet published. 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. 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. 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.

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.

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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 patents and for licensors, if they were to seek to do so, to stop infringement of patents that are licensed to us. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business. Additionally, prosecuting and maintaining intellectual property (particularly patent) rights are very costly endeavors, and for these and other reasons we may not pursue or obtain patent protection in all major markets. We do not know whether legal and government fees will increase substantially and therefore are unable to predict whether cost may factor into our global intellectual property strategy.

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

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

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 us or made known to the other party by us during the course of the other 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 and therefore be free to use such 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 products 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 our industry, we employ individuals who were previously employed at other companies in our industry or in related industries, 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

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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 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 could be an emerging growth company for up to five years from our initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our ordinary shares held by non-affiliates exceeds \$700 million as of September 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 March 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. 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 the price of our ordinary shares may be more volatile.

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.

The price of our ordinary shares is likely to be volatile, and purchasers of our ordinary shares could incur substantial losses.

Like other emerging life sciences companies, the market price of our ordinary shares is likely to 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;
- delays in the planned commercialization of MosaiQTM;
- speed and timing of adoption of MosaiQTM by key target customers,
- 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, conditions in the financial markets and the perception of our ability to raise additional funding;
- regulatory developments affecting MosaiQTM or our industry, including announcement of new adverse regulatory decisions in respect of MosaiQTM;
- announcements of studies and reports relating to our products, including MosaiQTM or those of our competitors;
- changes in economic performance or market valuations of our competitors;
 - actual or anticipated fluctuations in our annual and quarterly financial 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;

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release or expiry of lock-up or other transfer restrictions on our outstanding ordinary shares subject to such restrictions; and sales or perceived sales of additional ordinary shares.

In addition, the securities of life sciences companies have recently experienced significant volatility. 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.

Substantial future sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the price of our ordinary shares to decline, irrespective of the underlying performance of our business.

Additional sales of our ordinary shares in the public market, or the perception that these sales could occur, could cause the market price of our ordinary shares to decline. We had outstanding 25,408,950 ordinary shares as of March 31, 2016, of which approximately 13,596,081 ordinary shares were sold or issued pursuant to effective registration statements or resold pursuant to Rule 144 under the Securities Act, or Rule 144, and are freely transferable without restriction or additional registration under the Securities Act. In addition, approximately 2,000,000 ordinary shares were registered for public resale under an effective registration statement under the Securities Act and are freely transferable without restriction and approximately 9,812,869 ordinary shares were restricted or control securities that are available, or will be available, for resale subject to volume and other restrictions as applicable under Rule 144. In addition, as of March 31, 2016, 1,025,525 ordinary shares were subject to outstanding warrants at a weighted average exercise price of \$2.35 per share and 1,589,938 ordinary shares were subject to outstanding options at a weighted exercise price of \$7.86 per share. To the extent any of these shares are sold into the market, particularly in substantial quantities, the market price of our ordinary shares could decline.

We have never paid cash dividends and 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. In addition, pursuant to MidCap Facility, we are precluded from paying any cash dividends without MidCap's consent. Under Jersey, Channel Islands law, any payment of dividends would be subject to relevant legislation and our Amended Articles of Association 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.

Galen Partners LLP, Mrs. Deidre Cowan (the wife of our Chairman and Chief Executive Officer) and management own a significant percentage of our ordinary shares and will be able to exercise significant influence over matters subject to shareholder approval.

Certain entities affiliated with Galen Partners LLP, Mrs. Deidre Cowan (the wife of our Chairman and Chief Executive Officer), and our executive officers and directors, together with their respective affiliates, hold a substantial percentage of our outstanding ordinary shares. 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.

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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. During the evaluation of our internal controls over financial reporting, we identified a material weakness in our internal controls, and concluded that our internal controls over financial reporting was not effective as of March 31, 2016. For addition information, see "Item 9A. Management's Annual Report on Internal Control Over Financial Reporting." We cannot assure you that there will not be additional material weaknesses or significant deficiencies in our internal controls in the future.

We cannot guarantee that we will be able to satisfy the continued listing standards of The NASDAQ Global Market going forward.

Our ordinary shares are listed on NASDAQ. However, we cannot ensure that we will be able to satisfy the continued listing standards of NASDAQ 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 NASDAQ. 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 the ability of a holder of our ordinary shares to trade or obtain quotations on our ordinary 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 ordinary shares or warrants at or above the price you paid for such ordinary shares or at all.

The dilutive effect of our warrants could have an adverse effect on the future market price of our ordinary shares or otherwise adversely affect the interests of our ordinary shareholders.

As of March 31, 2015, there was an outstanding warrant to purchase 64,000 of our ordinary shares at an exercise price of \$9.38 per share, 850,000 outstanding pre-funded warrants to purchase 850,000 of our ordinary shares at a price of \$0.01 per share and outstanding warrants to purchase 111,525 of our ordinary shares at an exercise price of \$16.41 per share. These warrants are likely to be exercised if the market price of our ordinary shares equals or exceeds the applicable warrant's exercise price. To the extent such warrants are exercised, additional ordinary shares will be issued, which would dilute the ownership of existing shareholders.

Risks Related to Being a Jersey, Channel Islands Company Listing Ordinary Shares or Warrants

Our ordinary shares are issued under the laws of Jersey, Channel Islands, which may not provide the level of legal certainty and transparency afforded by incorporation in a United States state.

We are organized under the laws of the Jersey, Channel Islands, a British crown dependency that is an island located off the coast of Normandy, France. Jersey is not a member of the European Union. Jersey, Channel Islands legislation regarding companies is largely based on English corporate law principles. However, there can be no assurance that Jersey, Channel Islands law will not change in the future or that it will serve to protect investors in a similar fashion afforded under corporate law principles in the United States, which could adversely affect the rights of investors.

Beneficial holders of our ordinary shares through the Depository Trust Company will not be legal shareholders of our company and therefore will have no direct rights as shareholders and must act through their participating broker to exercise those rights. As a result of this restriction, we are unable to comply with NASDAQ's Direct Registration Program.

Under the laws of Jersey, Channel Islands, only holders of ordinary shares in the UK's CREST electronic system or holders of shares in certificated form may be recorded in our share register as legal shareholders.

Cede & Co., as nominee for the Depository Trust Company, or DTC, holds the ordinary shares sold in our public offerings on behalf of, and as nominee for, investors who purchase such shares. We and DTC have no contractual relationship. Investors who purchase the ordinary shares (although recorded as owners within the DTC system) are legally considered holders of beneficial interests in those shares only and will have no direct rights against us. Investors who purchase ordinary shares must look solely to their participating brokerage in the DTC system for payment of dividends, the exercise of voting rights attaching to the ordinary shares and for all other rights arising with respect to the ordinary shares.

Under our Amended Articles of Association, the minimum notice period required to convene a general meeting is 14 clear days. When a general meeting is convened, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw your ordinary shares from the DTC system to allow you to directly cast your vote with respect to any specific matter. In addition, a participating DTC brokerage firm may not be able to send voting instructions to you or carry out your voting instructions in a timely manner. We cannot assure you that you will receive voting materials in time to ensure that you can instruct your participating DTC brokerage, or its designee, to vote your shares. As a result, you may not be able to exercise your right to vote and you may lack

recourse if your ordinary shares are not voted as you requested. In addition, if you hold your shares indirectly through the DTC system, you will not be able to call a shareholder meeting.

As a result of Jersey, Channel Islands law restrictions described above, we are unable to comply with NASDAQ's Direct Registration Program requirements. NASDAQ Listing Rule 5210(c) requires that all securities listed on NASDAQ (except securities which are book-entry only) must be eligible for a Direct Registration Program operated by a clearing agency registered under Section 17A of the Exchange Act; provided, however, that a foreign issuer may follow its home country practice in lieu of this requirement if prohibited from complying by a law or regulation in its home country. As noted above, we are unable to comply with this requirement, and will follow our home country requirements providing that only holders of shares in the CREST electronic system or holders of shares in certificated form will be recorded in our share register. We do not intend to list our shares in the United Kingdom and, accordingly, we only anticipate issuing our shares in certificated form.

A change in our tax residence could have a negative effect on our future profitability.

We are organized under the laws of Jersey, Channel Islands. Our directors seek to ensure that our affairs are conducted in such a manner that we are not resident in any other jurisdiction for tax purposes. It is possible that in the future, whether as a result of a change in law or the practice of any relevant tax authority or as a result of any change in the conduct of our affairs following a review by our directors or for any other reason, we could become, or be regarded as having become, a resident in another higher tax jurisdiction. Should we become a tax resident in another jurisdiction, we may be subject to unexpected tax charges in such jurisdiction. Similarly, if the tax residency of any of our subsidiaries were to change from their current jurisdiction for any of the reasons listed above, we may be subject to similar tax consequences.

We may be or become classified as a passive foreign investment company for U.S. federal income tax purposes, which could result in materially adverse U.S. federal income tax consequences to U.S. investors in our ordinary shares.

A non-U.S. corporation will be a passive foreign investment company, or PFIC, for any taxable year in which (1) at least 75% of its gross income is passive income or (2) at least 50% of the value (determined on a quarterly basis) of its assets is attributable to assets that produce or are held for the production of passive income. Our status as a PFIC depends on certain facts outside of our control and the application of U.S. federal income tax rules that are not entirely clear. Accordingly, there can be no assurance that we will not be classified as a PFIC for our current taxable year or any future taxable year. If we are treated as a PFIC for any taxable year during which you hold our ordinary shares, such treatment could result in materially adverse U.S. federal income tax consequences to you if you are a U.S. taxable investor. For example, if we are or become a PFIC, you may become subject to increased tax liabilities under U.S. federal income tax laws and regulations, and will become subject to additional reporting requirements. Although we do not believe we were a PFIC for our taxable year ended March 31, 2016 and do not expect to be a PFIC for the taxable year ending March 31, 2017 or any future taxable year, we cannot assure you that we have not been or will not be a PFIC for any particular taxable year. U.S. investors considering an investment in our ordinary shares are urged to consult their tax advisors regarding our possible status as a PFIC.

U.S. withholding tax could apply to a portion of certain payments on the ordinary shares.

The United States has enacted rules, commonly referred to as "FATCA," that generally impose a new reporting and withholding regime with respect to certain U.S. source payments (including dividends and interest), gross proceeds from the disposition of property that can produce U.S. source interest and dividends and certain payments made by entities that are classified as financial institutions under FATCA. The governments of Jersey, Channel Islands and the United States have entered into an agreement with respect to the implementation of FATCA. Under this agreement, we do not expect to be subject to withholding under FATCA on any payments we receive. Similarly, as currently drafted, we do not expect that withholding under FATCA will apply to payments on the ordinary shares. However,

significant aspects of whether or how FATCA will apply to non-U.S. issuers like us remain unclear, and no assurance can be given that withholding under FATCA will not become relevant with respect to payments on the ordinary shares in the future. Even if FATCA were to become relevant to payments on the shares, it would not be applicable earlier than January 1, 2019. Prospective investors should consult their own tax advisors regarding the potential impact of FATCA, including the agreement relating to FATCA between the governments of Jersey and the United States, to an investment in the ordinary shares.

U.S. shareholders may not be able to enforce civil liabilities against us.

A number of our directors and executive officers and a number of directors of certain of our subsidiaries are not residents of the United States, and a substantial portion of the assets of such persons are located outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons.

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Judgments of U.S. courts may not be directly enforceable outside of the United States and the enforcement of judgments of U.S. courts outside of the United States may be subject to limitations. Investors may also have difficulties pursuing an original action brought in a court in a jurisdiction outside the United States for liabilities under the securities laws of the United States.

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties

Our UK corporate headquarters, including our development laboratory facility, and our manufacturing facility for conventional reagent products are located in Edinburgh, Scotland. We also have a manufacturing facility in Eysins, Switzerland, which we expect will become the principal manufacturing site for the MosaiQ™ consumable. Our U.S. corporate headquarters are located in Newtown, Pennsylvania. The table below provides selected information regarding our existing facilities, all of which are leased.

Facility/Use	Location	Size (sq. ft.)		
		Office	Laboratory	Expiration
UK Corporate Headquarters/Development Laboratory Facility	Edinburgh, Scotland	3,500	5,000	July 31, 2017
Manufacturing Operations—Conventional Reagents	Edinburgh, Scotland	6,200	16,000	August 30, 2016
MosaiQ™ Laboratory Facility	Edinburgh, Scotland	3,600	3,600	December 31, 2018
Manufacturing Operations—MosaiQ™	Eysins, Switzerland	13,600	31,600	March 15, 2020
U.S. Corporate Headquarters	Newtown, PA, USA	1,200	—	November 30, 2018
U.S. Direct Sales Operation	Chapel Hill, NC, USA	1,000	—	May 31, 2018

We believe 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. In November 2015, we entered into a lease for a 3.18 hectare plot of land at the Midlothian Biocampus near Edinburgh, Scotland. We are constructing a 92,000 square foot manufacturing, laboratory and office facility at this site to consolidate our Edinburgh, Scotland operations.

Item 3. Legal Proceedings

We are not currently a party to any pending legal proceedings that we believe could have a material adverse effect on our business or financial condition. However, we may be subject to various claims and legal actions arising in the ordinary course of business from time to time.

Item 4. Mine Safety Disclosures

Not applicable.

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PART II

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

Market Information

Commencing on May 27, 2014, the ordinary shares and warrants comprising the units issued in our initial public offering began trading separately on NASDAQ under the symbols “QTNT” and “QTNTW”, respectively. In connection with the initiation of separate trading of the ordinary shares and warrants, the trading of the units (which were listed under the symbol “QTNTU”) was suspended and the units were delisted from NASDAQ. The warrants expired on October 26, 2015 and, on that date, the warrants ceased trading and were delisted from NASDAQ. Prior to our initial public offering, there was no public market for our securities. On May 27, 2016, the last reported sale price of our ordinary shares on NASDAQ was \$10.755 per share.

The following table sets forth the high and low sales price per ordinary share reported on NASDAQ as traded for each of the quarters indicated:

	High	Low
Fiscal Year Ended March 31, 2016		
Fourth Quarter	\$16.00	\$6.50
Third Quarter	\$17.44	\$11.05
Second Quarter	\$19.95	\$12.78
First Quarter	\$17.15	\$13.04
Fiscal Year Ended March 31, 2015		
Fourth Quarter	\$18.03	\$12.35
Third Quarter	\$19.89	\$9.02
Second Quarter	\$10.98	\$7.49
First Quarter (1)	\$9.76	\$5.82

(1)Commencing May 27, 2014.
Shareholders

On May 27, 2016, there were 22 shareholders of record of our ordinary shares. This number does not include shareholders for whom shares were held in a “nominee” or “street” name.

Dividends

We have never declared or paid cash dividends on our ordinary shares. We currently intend to retain all available funds and any 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 complete 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.

Performance Graph

Below is a graph which compares the cumulative shareholder return on our ordinary shares from March 31, 2015 through March 31, 2016 against the cumulative total return for the same period on the NASDAQ Stock Market Composite Index and the NASDAQ Healthcare Index. The results are based on an assumed \$100 invested on March 31, 2015.

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Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents certain information about our equity compensation plans as of March 31, 2016:

	Number of securities to be issued upon exercise of outstanding options and rights	Weighted average exercise price of outstanding options and rights	Number of shares remaining available for future issuance
Equity compensation plans approved			
by shareholders (1)	1,827,633	\$ 6.84	468,391
Equity compensation plans not approved			
by shareholders	—	—	—

(1) Composed of the 2012 Option Plan, pursuant to which 626,072 ordinary shares are issuable upon exercise of outstanding options and rights at a weighted average exercise price of \$3.08, and the 2014 Stock Incentive Plan, pursuant to which 1,201,561 ordinary shares are issuable upon exercise of outstanding options and rights at a weighted average exercise price of \$8.80. At March 31, 2016, 453,100 ordinary shares remain available for future issuance under the 2014 Stock Incentive Plan.

Recent Sale of Unregistered Securities

Since April 1, 2015, we issued the following securities that were not registered under the Securities Act.

On August 3, 2015, pursuant to the MidCap Facility, we issued to MidCap a warrant to purchase 111,525 of our ordinary shares at an exercise price of \$16.14 per ordinary share. This warrant is exercisable for a term of ten years and contains cashless exercise provisions and customary, share-based anti-dilution protection provisions. Further warrants will be issued to MidCap in connection with each subsequent drawdown of funds by us under the MidCap Facility for new ordinary shares equal to 6.0% of the drawdown amount based on the market price of our ordinary shares at the time of issue.

On September 25, 2015, in connection with an amendment to the MidCap Facility, MidCap transferred to Oxford Finance LLC and Flexpoint MCLS SPV LLC certain of the purchase rights represented by the warrant that we previously issued to MidCap on August 3, 2015 in connection with the expansion of the MidCap Facility, and we, MidCap, Oxford and Flexpoint entered into new warrants in connection with such transfers. As a result of the amendment and such transfers, the lenders under the Facility hold warrants to exercise ordinary shares, and are committed to extend loans under the MidCap Facility, in the amounts and percentages indicated below:

Lender/Warrant Holder	Shares Issuable Upon Exercise	Loan Commitment Percentage
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	of		
	Warrants		
MidCap	66,915	60	%
Oxford	40,149	36	%
Flexpoint	4,461	4	%
Total	111,525	100	%

The above issuances were exempt from registration under the Securities Act under Section 4(a)(2) thereof, as transactions by an issuer not involving a public offering. No underwriters were used in connection with any of the foregoing transactions. The purchasers of securities in each such transaction represented that they were accredited investors as defined in Regulation D and that they were acquiring the securities for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof, and appropriate legends were affixed to the securities.

Item 6. Selected Consolidated Financial Data

The following tables summarize our consolidated financial and other data. The consolidated statement of income data for the years ended March 31, 2016, 2015 and 2014 and the consolidated balance sheet data as of March 31, 2016 and 2015 have been derived from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statement of income data for the year ended March 31, 2013 and 2012 and the consolidated balance sheet data as of March 31, 2014 and 2013 have been derived from our audited consolidated financial statements not included in this Annual Report on Form 10-K.

Our historical results are not necessarily indicative of the results that may be expected in the future. You should read the following selected financial data together with “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and accompanying notes included elsewhere in this Annual Report on Form 10-K. The selected financial data in this section are not intended to replace our financial statements and the accompanying notes.

	Year ended March 31,				
	2016	2015	2014	2013	2012
	(in thousands, except share and per share data)				
Consolidated statement of loss:					
Revenue:					
Product sales	\$18,022	\$17,658	\$16,987	\$13,753	\$11,550
Other revenues	500	750	2,768	618	669
Total revenue	18,522	18,408	19,755	14,371	12,219
Cost of revenue	(9,658)	(9,763)	(8,406)	(7,169)	(6,749)
Gross profit	8,864	8,645	11,349	7,202	5,470
Operating expenses:					
Sales and marketing	(3,073)	(2,750)	(2,705)	(2,252)	(1,674)
Research and development, net of government grants	(28,781)	(19,216)	(8,066)	(2,617)	(1,749)
General and administrative expense:					
Compensation expense in respect of share					
options and management equity incentives	(2,004)	(1,138)	(933)	(471)	—
Other general and administrative expenses	(24,094)	(15,255)	(8,537)	(6,353)	(6,011)
Total general and administrative expense	(26,098)	(16,393)	(9,470)	(6,824)	(6,011)
Total operating expense	(57,952)	(38,359)	(20,241)	(11,693)	(9,434)
Operating loss	(49,088)	(29,714)	(8,892)	(4,491)	(3,964)
Other income (expense):					
Interest expense, net	(4,151)	(2,315)	(1,076)	(234)	(340)
Change in financial liability for share warrants	15,857	(22,966)	—	—	—
Other, net	3,504	(4,064)	(197)	11	(169)
Other income (expense), net	15,210	(29,345)	(1,273)	(223)	(509)
Loss before income taxes	(33,878)	(59,059)	(10,165)	(4,714)	(4,473)
Provision for income taxes	—	—	—	—	—
Net loss	\$(33,878)	\$(59,059)	\$(10,165)	\$(4,714)	\$(4,473)
Net loss available to ordinary shareholders					
- basic and diluted	\$(33,878)	\$(59,059)	\$(10,165)	\$(4,714)	\$(4,473)

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Loss per share - basic and diluted	\$(1.73) \$(4.00) \$(54.41) \$(62.97) \$(78.04)
Weighted-average shares outstanding - basic and diluted	19,558,152	14,773,386	186,817	74,866	57,317

	As of March 31,			
	2016	2015	2014	2013
	(in thousands)			
Consolidated balance sheet data:				
Cash and cash equivalents	\$44,100	\$37,525	\$7,192	\$4,219
Total assets	119,750	80,204	28,296	12,891
Long-term debt	27,910	9,853	13,593	3,000
Total liabilities	73,027	81,819	30,581	7,931
Total shareholders' funds (deficit)	\$46,723	\$(1,615)	\$(31,536)	\$(23,061)

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 the financial statements and the related notes to those statements included later in this Annual Report on Form 10-K. In addition to historical financial information, the following discussion contains forward-looking statements that reflect our plans, estimates, beliefs and expectations that involve risks and uncertainties. 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, particularly in "Risk Factors."

Overview

We were incorporated in Jersey, Channel Islands on January 28, 2012. On February 16, 2012, we acquired the entire issued share capital of Alba Bioscience Limited (or Alba), Quotient Biodiagnostics, Inc. (or QBDI) and QBD (QSIP) Limited (or QSIP) from Quotient Biodiagnostics Group Limited (or QBDG), our predecessor.

The acquisition of Alba, QBDI and QSIP by us is treated for accounting purposes as a combination of entities under common control as these entities were all controlled by QBDG prior to their acquisition by us. We recognized the assets and liabilities of Alba, QBDI and QSIP at their carrying amounts in the financial statements of those companies. We are a continuation of QBDG and its subsidiaries and, accordingly, our consolidated financial statements include the assets, liabilities and results of operations of the subsidiaries transferred since their inception.

Our Business

We are a commercial-stage diagnostics company committed to reducing healthcare costs and improving patient care through the provision of innovative tests within established markets. Our initial focus is on blood grouping and donor disease screening, which is commonly referred to as transfusion diagnostics. Blood grouping involves specific procedures performed at donor or patient testing laboratories to characterize blood, which includes antigen typing and antibody identification. Disease screening involves the screening of donor blood for unwanted pathogens using two different methods, a serological approach (testing for specific antigens or antibodies) and a molecular approach (testing for nucleic acid).

We have over 30 years of experience developing, manufacturing and commercializing conventional reagent products used for blood grouping within the global transfusion diagnostics market. We are developing MosaiQ™, our proprietary technology platform, to better address the comprehensive needs of this large and established market. We believe MosaiQ™ has the potential to transform transfusion diagnostics, significantly reducing the cost of blood grouping in donor and patient testing environments while improving patient outcomes.

We currently operate as one business segment with over 330 employees in the United Kingdom, Switzerland and the United States. Our principal markets are the United States, Europe and Japan. Based on the location of the customer, revenues outside the United States accounted for 52%, 55% and 51% of total revenue during the years ended March 31, 2016, 2015 and 2014, respectively.

We have incurred net losses and negative cash flows from operations in each year since we commenced operations in 2007. As of March 31, 2016, we had an accumulated deficit of \$108.2 million. We expect our operating losses will continue for at least the next fiscal year as we continue our investment in the development and commercialization of MosaiQ™. Our total revenue was \$18.5 million for the year ended March 31, 2016, \$18.4 million for the year ended March 31, 2015, and \$19.8 million for the year ended March 31, 2014. Our net loss was \$33.9 million for the year ended March 31, 2016, \$59.1 million for the year ended March 31, 2015, and \$10.2 million for the year ended

March 31, 2014.

On April 30, 2014, we completed our initial public offering and issued 5,000,000 units at \$8.00 per unit. We raised net proceeds of \$37.2 million after deducting underwriting discounts and commissions, while other costs of the offering amounted to \$3.6 million. Each unit comprised one ordinary share and one warrant and each warrant permitted the holder, prior to October 26, 2015, to subscribe for 0.8 of one new ordinary share at an exercise price equivalent to \$8.80 per underlying ordinary share. At the time of the offering, we recorded a financial liability in our financial statements amounting to \$8.5 million, which represented the value ascribed to the warrants attributable to our initial public offering of units. On May 27, 2014, our ordinary shares and warrants began trading separately on The NASDAQ Global Market and the units were delisted. On October 26, 2015, the warrants expired and were delisted. Of the 5,000,000 warrants issued, 4,981,052 were exercised prior to the expiration date and 18,948 were cancelled on October 26, 2015. The exercise of the warrants resulted in the issuance of 3,984,823 ordinary shares and we received proceeds of \$35.1 million. We recorded the change in the market value of the warrants between the date of our initial public offering and the expiration date as an expense or income within net other income (expense) in our income statement. For the year ended March 31, 2015, we recorded an expense of \$23.0 million and in the year ended March 31, 2016, we recorded income of \$15.9 million.

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On November 25, 2014, we entered into subscription agreements with certain institutional and individual accredited investors for the private placement of 2,000,000 newly issued ordinary shares at a price of \$9.50 per share and 850,000 newly issued pre-funded warrants at a price of \$9.49 per warrant, amounting to an aggregate subscription price of approximately \$27.1 million. Each pre-funded warrant permits the holder to subscribe for one new ordinary share at an exercise price of \$0.01 per pre-funded warrant.

On January 29, 2015, we entered into a subscription agreement with Ortho-Clinical Diagnostics Finco S.Á.R.L., an affiliate of Ortho, for the private placement of 444,445 newly issued ordinary shares at a price of \$22.50 per share and 666,665 newly issued 7% cumulative redeemable preference shares, of no par value, at a price of \$22.50 per share, for an aggregate subscription price of approximately \$25 million.

On August 3, 2015, we entered into an amended agreement with MidCap to expand our existing secured term loan facility from \$15.0 million to \$30.0 million. MidCap also agreed to make available, subject to certain conditions, additional credit facilities totaling \$20.0 million. The amended facility agreement with MidCap included a covenant to maintain cash balances above \$10 million.

On February 10, 2016, we completed a public offering of 4,444,445 newly issued ordinary shares at a price of \$9.00 per share. The net proceeds from this offering were \$36.8 million, net of underwriting discounts and other offering expenses, while the other costs of the offering amounted to \$0.8 million.

Revenue

We generate product sales revenue from the sale of conventional reagent products directly to hospitals, donor collection agencies and independent testing laboratories in the United States, the United Kingdom and to distributors in Europe and the rest of the world, and indirectly through sales to our OEM customers. We recognize revenues in the form of product sales when the goods are shipped. Products sold by standing purchase orders as a percentage of product sales revenue were 73% for the year ended March 31, 2016, 72% for the year ended March 31, 2015 and 71% for the year ended March 31, 2014. We also provide product development services to our OEM customers. We recognize revenue from these contractual relationships in the form of product development fees, which are included in Other revenues. For a description of our revenue recognition policies, see “—Critical Accounting Policies and Significant Judgments and Estimates—Revenue Recognition and Accounts Receivable.”

Our revenue is denominated in multiple currencies. Sales in the United States and to certain of our OEM customers are denominated in U.S. Dollars. Sales in Europe and the rest of the world are denominated primarily in U.S. Dollars, Pounds Sterling or Euros. Our expenses are generally denominated in the currencies in which our operations are located, which are primarily in the United Kingdom, Switzerland and the United States. We operate globally and therefore changes in foreign currency exchange rates may become material to us in the future due to factors beyond our control. See “—Quantitative and Qualitative Disclosure About Market Risk—Foreign Currency Exchange Risk.”

Cost of revenue and operating expenses

Cost of revenue consists of direct labor expenses, including employee benefits, overhead expenses, material costs and freight costs, along with the depreciation of manufacturing equipment and leasehold improvements. Our gross profit represents total revenue less the cost of revenue, and gross margin represents gross profit expressed as a percentage of total revenue. Our gross margin was 48% for year ended March 31, 2016, 47% for the year ended March 31, 2015 and 57% for the year ended March 31, 2014. Excluding other revenues, which consist of product development fees, our gross margin on product sales was 46% for the year ended March 31, 2016, 45% for the years ended March 31, 2015 and 50% for the year ended March 31, 2014. We expect our overall cost of revenue to increase in absolute U.S. Dollars as we continue to increase our product sales volumes. However, we also believe that we can achieve

efficiencies in our manufacturing operations, primarily through increasing production volumes, which should improve our gross margin on product sales.

Our sales and marketing expenses include costs associated with our sales organization for conventional reagent products, including our direct sales force, as well as our marketing and customer service personnel. These expenses consist principally of salaries, commissions, bonuses and employee benefits, as well as travel costs related to our sales activities. These expenses also include direct and indirect costs associated with our product marketing activities. We expense all sales and marketing costs as incurred. We expect sales and marketing expense to increase in absolute U.S. Dollars, primarily as a result of commissions on increased product sales in the United States, but decline as a percentage of product sales.

Our research and development expenses include costs associated with performing research, development, field trials and our regulatory activities, as well as production costs incurred in advance of the commercial launch of MosaiQ™. Research and development expenses include research personnel-related expenses, fees for contractual and consulting services, travel costs,

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laboratory supplies and depreciation of laboratory equipment. In the year ended March 31, 2015, these expenses also included the costs of our intellectual property license with TTP relating to MosaiQ™.

We expense all research and development costs as incurred, net of government grants received and tax credits. In 2015, changes in UK tax legislation enabled our UK subsidiary to claim certain tax credits on its research and development expenditures. Previously, these tax credits increased the unutilized tax losses of our UK subsidiary, but are now being claimed and are included as an offset to our research and development expenses. Our research and development efforts are focused on developing new products and technologies for the global transfusion diagnostics market. We segregate research and development expenses for the MosaiQ™ project from expenses for other research and development projects. We do not maintain detailed records of these other costs by activity. We expect overall research and development expense to increase in absolute U.S. Dollars as we focus on completing the development of MosaiQ™.

Our general and administrative expenses include costs for our executive, accounting and finance, legal, corporate development, information technology and human resources functions. We expense all general and administrative expenses as incurred. These expenses consist principally of salaries, bonuses and employee benefits for the personnel performing these functions, including travel costs. These expenses also include share-based compensation, professional service fees (such as audit, tax and legal fees), costs related to our Board of Directors, and general corporate overhead costs, which includes depreciation and amortization. We expect our general and administrative expenses to increase as our business develops and also due to the costs of operating as a public company, such as additional legal, accounting and corporate governance expenses, including expenses related to compliance with the Sarbanes-Oxley Act, directors' and officers' insurance premiums and investor relations expenses.

Net interest expense consists primarily of interest charges on our loan balances and the amortization of debt issuance costs, as well as accrued dividends on the 7% cumulative redeemable preference shares issued in January 2015. We amortize debt issuance costs over the life of the loan and report them as interest expense in our statements of operations.

Other income (expense), net consists primarily of realized exchange fluctuations resulting from the settlement of transactions in currencies other than the functional currencies of our businesses. Monetary assets and liabilities that are denominated in foreign currencies are measured at the period-end closing rate with resulting unrealized exchange fluctuations. The functional currencies of our businesses are Pounds Sterling, Swiss Franc and U.S. Dollars depending on the entity. In the years ended March 31, 2016 and 2015 net other expense also includes the change in the fair value of our warrants, asset write-downs related to the conversion of the Eysins, Switzerland facility and certain other non-recurring items as mentioned below under “—Results of Operations— Comparison of Years ended March 31, 2016 and 2015— Other income (expense).”

Results of Operations

Comparison of Years ended March 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.

	Years ended March 31, 2016		2015		Change	
	Amount	% of revenue	Amount	% of revenue	Amount	%
(in thousands, except percentages)						
Revenue:						
Product sales	\$18,022	97	% \$17,658	96	% \$364	2
Other revenues	500	3	% 750	4	% (250)	-33
Total revenue	18,522	100	% 18,408	100	% 114	1
Cost of revenue	9,658	52	% 9,763	53	% (105)	-1
Gross profit	8,864	48	% 8,645	47	% 219	3
Operating expenses:						
Sales and marketing	3,073	17	% 2,750	15	% 323	12
Research and development	28,781	155	% 19,216	104	% 9,565	50
General and administrative	26,098	141	% 16,393	89	% 9,705	59
Total operating expenses	57,952	313	% 38,359	208	% 19,593	51
Operating (loss)	(49,088)	-265	% (29,714)	-161	% (19,374)	65
Other income (expense):						
Interest expense, net	(4,151)	-22	% (2,315)	-13	% (1,836)	79
Other, net	19,361	105	% (27,030)	-147	% 46,391	—
Total other income (expense), net	15,210	82	% (29,345)	-159	% 44,555	-152
Loss before income taxes	(33,878)	-183	% (59,059)	-321	% 25,181	-43
Provision for income taxes	—	0	% —	0	% —	—
Net loss	\$(33,878)	-183	% \$(59,059)	-321	% \$25,181	-43

Revenue

Total revenue increased by 1% to \$18.5 million for the year ended March 31, 2016, compared with \$18.4 million for the year ended March 31, 2015. Product sales revenue increased by 2% to \$18.0 million for the year ended March 31, 2016, compared with \$17.7 million for the year ended March 31, 2015. Higher product sales volumes were offset by a \$1.0 million negative impact of a stronger U.S. dollar relative to the British Pound and Euro. Products sold by standing purchase order were 73% of product sales for the year ended March 31, 2016, compared with 72% for the year ended March 31, 2015. Total revenue for the years ended March 31, 2016 and 2015 also included product development revenues of \$0.5 million and \$0.8 million, respectively.

The below table sets forth revenue by product group:

Years ended March 31,

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	2016		2015		Change	
	Amount	% of revenue	Amount	% of revenue	Amount	%
(in thousands, except percentages)						
Revenue:						
Product sales - OEM customers	\$12,165	66	% \$12,377	67	% \$(212)	-2 %
Product sales - direct customers						
and distributors	5,857	32	% 5,281	29	% 576	11 %
Other revenues	500	3	% 750	4	% (250)	-33 %
Total revenue	\$18,522	100	% \$18,408	100	% \$114	1 %

OEM Sales. Product sales to OEM customers decreased 2% to \$12.2 million for the year ended March 31, 2016, compared with \$12.4 million for the year ended March 31, 2015. Higher product sales volumes and better pricing on sales to existing OEM customers were offset by the negative impact of a stronger U.S. dollar relative to the British Pound and Euro.

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Direct Sales to Customers and Distributors. Direct product sales increased 11% to \$5.9 million for the year ended March 31, 2016 compared with \$5.3 million for the year ended March 31, 2015. Direct sales in the United States increased by 17%, which was mainly attributable to sales of our reagent red blood cell products and recently launched new products. Direct sales outside the United States decreased by 6% as a result of our decision to rationalize our product offering in Europe and the negative impact of a stronger U.S. dollar relative to the British Pound and Euro.

Other Revenues. Other revenues of \$0.5 million for the year ended March 31, 2016 consisted of product development fees associated with the development of a range of rare antisera products for an OEM customer. During the year ended March 31, 2015, we recognized \$0.8 million of product development fees related to the same development program.

Cost of revenue and gross margin

Cost of revenue decreased by 1% to \$9.7 million for the year ended March 31, 2016, compared with \$9.8 million for the year ended March 31, 2015. Costs associated with greater sales volumes were mostly offset by foreign exchange effects and efficiencies in our manufacturing operations.

Gross profit on total revenue in the year ended March 31, 2016 was \$8.9 million, an increase of 3% when compared with \$8.6 million in the year ended March 31, 2015. The increase was mainly attributable to greater gross profit on product sales, which offset a \$0.3 million decrease in other revenues. Excluding other revenues, gross profit on product sales in the year ended March 31, 2016 was \$8.4 million, an increase of 5% when compared with \$7.9 million in the year ended March 31, 2015. The gross profit on product sales improvement was mainly attributable to the positive impact of greater sales volumes and better pricing on sales to existing OEM customers, offset by the negative impact of foreign exchange rate movements.

Gross margin, which represents gross profit expressed as a percentage of total revenue, was 48% for the year ended March 31, 2016, compared with 47% for the year ended March 31, 2015. Gross margin on product sales increased to 46% for the year ended March 31, 2016, compared with 45% for the year ended March 31, 2015.

Sales and marketing expenses

Sales and marketing expense increased by 12% to \$3.1 million for the year ended March 31, 2016, compared with \$2.8 million for the year ended March 31, 2015. The increase was mainly attributable to higher advertising and promotional costs. As a percentage of total revenue, sales and marketing expenses were 17% for the year ended March 31, 2016, compared with 15% for the year ended March 31, 2015.

Research and development expenses

	Years ended March 31,		2015		Change	
	2016		2015		Amount	%
	Amount	% of revenue	Amount	% of revenue	Amount	%
(in thousands, except percentages)						
Research and development expenses:						
MosaiQ™ research and development	\$26,624	144	% \$17,661	96	% \$8,963	51 %
Other research and development	2,556	14	% 2,058	11	% 498	24 %
Tax credits and grants	(399)	-2	% (503)	-3	% 104	-21 %
Total research and development	\$28,781	155	% \$19,216	104	% \$9,565	50 %

expenses

Research and development expenses increased by \$9.6 million to \$28.8 million for the year ended March 31, 2016, compared with \$19.2 million for the year ended March 31, 2015. As a percentage of total revenue, research and development expenses increased to 155% for the year ended March 31, 2016, compared with 104% for the year ended March 31, 2015. This reflected incremental costs associated with the commercial scale-up of MosaiQ™, including initial production costs, which are currently expensed as research and development, as well as development activities associated with new conventional reagent product introductions. Research and development expenses for the year ended March 31, 2015 also included a \$1.0 million expense related to the costs of our intellectual property license with TTP for MosaiQ™.

Grant income and tax credits included \$0.4 million of tax credits in the year ended March 31, 2016 and \$0.5 million of grant income in the year ended March 31, 2015. Changes in UK tax legislation now enable our UK subsidiary to claim certain tax credits on its

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research and development expenditures. Previously, these tax credits increased the unutilized tax losses of our UK subsidiary, but are now being claimed and are included as an offset to our research and development expenses.

General and administrative expenses

General and administrative expenses increased by 59% to \$26.1 million for the year ended March 31, 2016, compared with \$16.4 million for the year ended March 31, 2015, reflecting greater personnel-related costs, increased facility rental charges and increased corporate costs. We recognized \$2.0 million of stock compensation expense in the year ended March 31, 2016 compared with \$1.1 million in the year ended March 31, 2015. As a percentage of total revenue, general and administrative expenses increased to 141% for the year ended March 31, 2016, compared with 89% for the year ended March 31, 2015.

Other income (expense)

Net interest expense was \$4.2 million for the year ended March 31, 2016, compared with \$2.3 million for the year ended March 31, 2015. Interest expense in the years ended March 31, 2016 and March 31, 2015 included interest charges on our borrowings from MidCap Financial LLC (“MidCap Financial”), which bore interest at LIBOR plus 6.7% (with a LIBOR floor of 2.00%). Borrowings from MidCap Financial amounted to \$15.0 million during the year ended March 31, 2015. During the year ended March 31, 2016, borrowings from MidCap Financial from April 1, 2015 to July 1, 2015 were \$15.0 million, then decreased to \$14.5 million from July 1, 2015 to August 3, 2015 as a result of scheduled principal amortization and then increased to \$30.0 million as a result of the increase in our credit facility. In the year ended March 31, 2016, net interest expense also included \$1.1 million of accrued dividends on the 7% cumulative redeemable preference shares issued in January 2015, compared with \$0.2 million of such dividends in the year ended March 31, 2015 and \$1.5 million of amortization of deferred funding costs compared with \$0.8 million of amortization of deferred funding costs in the year ended March 31, 2015.

Other income for the year ended March 31, 2016 included income of \$15.9 million related to the change in the fair value of the warrants issued at the time of our initial public offering and foreign exchange gains of \$4.1 million arising on monetary assets and liabilities denominated in foreign currencies offset by \$0.6 million of previously deferred fees that were expensed as a result of the expansion of our MidCap Facility in August 2015.

Other expense for the year ended March 31, 2015 included an expense of \$23.0 million related to the change in the fair value of the warrants issued at the time of our initial public offering. It also included \$3.8 million costs incurred in relation to the Ortho Agreement and other advisory fees, an exceptional charge of \$0.6 million related to the portion of fees associated with our initial public offering that were attributable to the issuance of the warrants, an expense of \$0.4 million related to the settlement of a dispute with Scottish National Blood Transfusion Service, \$0.4 million of asset write-downs related to the conversion of the Eysins, Switzerland facility and \$1.1 million of foreign exchange gains arising on monetary assets and liabilities denominated in foreign currencies.

Comparison of Years ended March 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.

	Year ended March 31, 2015		2014		Change	
	Amount	% of revenue	Amount	% of revenue	Amount	%
(in thousands, except percentages)						
Revenue:						
Product sales	\$ 17,658	96	% \$ 16,987	86	% \$ 671	4 %
Other revenues	750	4	% 2,768	14	% (2,018)	0 %
Total revenue	18,408	100	% 19,755	100	% (1,347)	-7 %
Cost of revenue	9,763	53	% 8,406	43	% 1,357	16 %
Gross profit	8,645	47	% 11,349	57	% (2,704)	-24 %
Operating expenses:						
Sales and marketing	2,750	15	% 2,705	14	% 45	2 %
Research and development	19,216	104	% 8,066	41	% 11,150	138 %
General and administrative	16,393	89	% 9,470	48	% 6,923	73 %
Total operating expenses	38,359	208	% 20,241	102	% 18,118	90 %
Operating (loss)	(29,714)	-161	% (8,892)	-45	% (20,822)	234 %
Other expense:						
Interest expense, net	(2,315)	-13	% (1,076)	-5	% (1,239)	115 %
Other, net	(27,030)	-147	% (197)	-1	% (26,833)	—
Total other expense, net	(29,345)	-159	% (1,273)	-6	% (28,072)	—
Loss before income taxes	(59,059)	-321	% (10,165)	-51	% (48,894)	481 %
Provision for income taxes	—	0	% —	0	% —	—
Net loss	\$(59,059)	-321	% \$(10,165)	-51	% \$(48,894)	481 %

Revenue

Total revenue decreased by 7% to \$18.4 million for the year ended March 31, 2015, compared with \$19.8 million for the year ended March 31, 2014. Product sales revenue increased by 4% to \$17.7 million for the year ended March 31, 2015, compared with \$17.0 million for the year ended March 31, 2014. Higher product sales volumes were offset by a \$0.3 million negative impact of a stronger U.S. dollar relative to the British Pound and Euro. Products sold by standing purchase order were 72% of product sales for the year ended March 31, 2015, compared with 71% for the year ended March 31, 2014. Total revenue for the years ended March 31, 2015 and 2014 also included revenue related to our product development services of \$0.8 million and \$2.8 million, respectively.

The below table sets forth revenue by product group:

	Year ended March 31, 2015		2014		Change	
	Amount	% of revenue	Amount	% of revenue	Amount	%
(in thousands, except percentages)						
Revenue:						

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Product sales - OEM customers	\$12,377	67	%	\$11,768	60	%	\$609	5 %
Product sales - direct customers								
and distributors	5,281	29	%	5,219	26	%	62	1 %
Other revenues	750	4	%	2,768	14	%	2,018	0 %
Total revenue	\$18,408	100	%	\$19,755	100	%	\$(1,347)	-7 %

OEM Sales. Product sales to OEM customers increased 5% to \$12.4 million for the year ended March 31, 2015, compared with \$11.8 million for the year ended March 31, 2014. Higher product sales volumes were offset by the negative impact of a stronger U.S. dollar relative to the British Pound and Euro. This growth was primarily driven by increased sales of our whole blood control products to existing OEM customers.

Direct Sales to Customers and Distributors. Direct product sales increased 1% to \$5.3 million for the year ended March 31, 2015 compared with \$5.2 million for the year ended March 31, 2014. Direct sales in the United States increased by 18%, which was

primarily driven by sales of our reagent red blood cell products. Direct sales outside the United States decreased by 29% as a result of our decision to rationalize our product offering in Europe and the negative impact of a stronger U.S. dollar relative to the British Pound and Euro.

Other Revenues. Other revenues of \$0.8 million for the year ended March 31, 2015 consisted of product development revenues associated with the development of a range of rare antisera products for an OEM customer. During the year ended March 31, 2014, we recognized \$2.8 million of product development fees related to the same development program.

Cost of revenue and gross margin

Cost of revenue increased by 16% to \$9.8 million for the year ended March 31, 2015, compared with \$8.4 million for the year ended March 31, 2014, reflecting growth in product sales volumes, higher shipping costs and incremental conventional reagent manufacturing costs. Gross profit on total revenue in the year ended March 31, 2015 was \$8.6 million, a decrease of 24% when compared with \$11.3 million in the year ended March 31, 2014. The decrease was mainly attributable to a \$2.0 million decrease in other revenues.

Excluding other revenues, gross profit on product sales in the year ended March 31, 2015 was \$7.9 million, a decrease of 8% when compared with \$8.6 million in the year ended March 31, 2014. The decrease was attributable to the impact of adverse exchange rate movements, higher shipping costs and incremental conventional reagent manufacturing costs, which offset the positive impact of higher sales volumes.

Gross margin, which represents gross profit expressed as a percentage of total revenue, was 47% for the year ended March 31, 2015, compared with 57% for the year ended March 31, 2014. Gross margin on product sales decreased to 45% for the year ended March 31, 2015, compared with 51% for the year ended March 31, 2014. The 2015 gross margin was affected by the impact of adverse exchange rate movements, higher shipping costs and incremental conventional reagent manufacturing costs.

Sales and marketing expenses

Sales and marketing expense increased by 2% to \$2.8 million for the year ended March 31, 2015, compared with \$2.7 million for the year ended March 31, 2014. The increase resulted primarily from commissions paid on greater direct product sales in the United States. As a percentage of total revenues, sales and marketing expenses were 15% for the year ended March 31, 2015, compared with 14% for the year ended March 31, 2014.

Research and development expenses

	Year ended March 31,		2014		Change	
	2015		2014		Amount	%
	Amount	% of revenue	Amount	% of revenue	Amount	%
(in thousands, except percentages)						
Research and development expenses:						
MosaiQ™ research and development	\$17,661	96	% \$6,712	34	% \$10,949	163%
Other research and development	2,058	11	% 1,788	9	% 270	15%
Tax credits and grants	(503)	-3	% (434)	-2	% (69)	—
Total research and development	\$19,216	104	% \$8,066	41	% \$11,150	138%

Expenses

Research and development expenses increased by \$11.2 million to \$19.2 million for the year ended March 31, 2015, compared with \$8.1 million for the year ended March 31, 2014. As a percentage of total revenue, research and development expenses increased to 104% for the year ended March 31, 2015, compared with 41% for the year ended March 31, 2014. This reflected increased expenditure on the MosaiQ™ project following the completion of our initial public offering and development activities associated with new conventional reagent product introductions. Research and development expenses for the year ended March 31, 2015 also included a \$1.0 million expense related to the costs of our intellectual property license with TTP for MosaiQ™.

Grant income and tax credits included \$0.5 million of tax credits in the year ended March 31, 2015 and \$0.4 million of grant income in the year ended March 31, 2014. Changes in UK tax legislation enabled our UK subsidiary to claim certain tax credits on its research and development expenditures. Previously, these tax credits increased the unutilized tax losses of our UK subsidiary, but in the year ended March 31, 2015 were now being claimed and included as an offset to our research and development expenses.

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General and administrative expenses

General and administrative expenses increased by 73% to \$16.4 million for the year ended March 31, 2015, compared with \$9.5 million for the year ended March 31, 2014, reflecting greater personnel-related costs, increased facility rental charges and increased corporate costs, including costs related to our transition to a public company. We recognized \$1.1 million of stock compensation expense in the year ended March 31, 2015 compared with \$0.9 million in the year ended March 31, 2014. As a percentage of total revenue, general and administrative expenses increased to 89% for the year ended March 31, 2015, compared with 48% for the year ended March 31, 2014.

Other expense

Net interest expense was \$2.3 million for the year ended March 31, 2015, compared with \$1.1 million for the year ended March 31, 2014. Interest expense in the year ended March 31, 2015 primarily consisted of interest charges on \$15.0 million of borrowings from MidCap Financial, which bore interest at LIBOR plus 6.7% (with a LIBOR floor of 2.00%). It also included \$0.8 million of amortization of costs related to the MidCap Financial borrowings and \$0.2 million of accrued dividends on the 7% cumulative redeemable preference shares issued in January 2015. Interest expense in the year ended March 31, 2014 primarily consisted of interest charges on \$3.0 million of borrowings from Haemonetics, Inc., which bore interest at 7.5% per annum. Part of the proceeds of the MidCap Financial borrowings was used to repay the Haemonetics borrowings in full on December 9, 2013. Net interest expense for the year ended March 31, 2014 also included a charge of \$0.3 million related to unamortized fees associated with the Haemonetics borrowings.

Other expense for the year ended March 31, 2015 included an expense of \$23.0 million related to the change in the fair value of the warrants issued at the time of our initial public offering. It also included \$3.8 million costs incurred in relation to the Ortho Agreement and other advisory fees, an exceptional charge of \$0.6 million related to the portion of fees associated with our initial public offering that were attributable to the issuance of the warrants, an expense of \$0.4 million related to the settlement of a dispute with Scottish National Blood Transfusion Service, \$0.4 million of asset write-downs related to the conversion of the Eysins, Switzerland facility and \$1.1 million of foreign exchange gains arising on monetary assets and liabilities denominated in foreign currencies. Other expense in the year ended March 31, 2014 included \$0.2 million of foreign exchange losses arising on monetary assets and liabilities denominated in foreign currencies.

Quarterly Results of Operations

The following table sets forth selected unaudited consolidated quarterly statements of operations data for our eight most recent completed fiscal quarters. We have prepared the consolidated quarterly operations data on a basis consistent with the audited consolidated financial statements included elsewhere in this Annual Report. 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 this 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.

	2014			2015			2016		
	Jun 30	Sept 30	Dec 31	Mar 31	Jun 30	Sept 30	Dec 31	Mar 31	
	(in thousands, except percentages)								
Revenue:									
Product sales	\$5,267	\$4,527	\$3,962	\$3,902	\$4,850	\$4,273	\$4,354	\$4,545	
Other revenues	650	—	100	—	—	—	—	500	
Total revenue	5,917	4,527	4,062	3,902	4,850	4,273	4,354	5,045	
Cost of revenue	(2,451)	(2,706)	(2,204)	(2,404)	(2,751)	(2,124)	(2,225)	(2,558)	
Gross profit	3,466	1,822	1,857	1,498	2,099	2,149	2,129	2,487	
Operating expenses:									
Sales and marketing	(697)	(609)	(789)	(655)	(658)	(774)	(918)	(723)	
Research and development	(3,685)	(5,435)	(4,453)	(5,643)	(6,810)	(8,381)	(6,931)	(6,659)	
General and administrative	(3,490)	(3,998)	(3,943)	(4,961)	(5,124)	(5,965)	(7,059)	(7,950)	
Total operating expenses	(7,872)	(10,043)	(9,185)	(11,259)	(12,592)	(15,120)	(14,908)	(15,332)	
Operating profit (loss)	(4,405)	(8,221)	(7,327)	(9,761)	(10,493)	(12,971)	(12,779)	(12,845)	
Other income (expense):									
Interest expense, net	(534)	(539)	(541)	(701)	(797)	(1,061)	(1,134)	(1,159)	
Other, net	2,324	(2,960)	(34,435)	8,041	1,136	9,599	4,135	4,491	
Total other income (expense), net	1,789	(3,498)	(34,976)	7,340	339	8,538	3,001	3,332	
Loss before income taxes	(2,616)	(11,719)	(42,303)	(2,421)	(10,154)	(4,433)	(9,778)	(9,513)	
Provision for income taxes	—	—	—	—	—	—	—	—	
Net loss	\$(2,616)	\$(11,719)	\$(42,303)	\$(2,421)	\$(10,154)	\$(4,433)	\$(9,778)	\$(9,513)	
% of Product Sales from	71 %	70 %	74 %	74 %	74 %	71 %	71 %	77 %	

Standing

Purchase Orders

Our quarterly product sales can fluctuate depending upon the shipment cycles for our red blood cell-based products, which account for approximately two-thirds of our current product sales. For these products, we typically experience 13 shipping cycles per year. This equates to three shipments of each product per quarter, except for one quarter per year when four shipments occur. In fiscal 2015 and in fiscal 2016, the greatest impact of extra product shipments occurred in our first quarter. The timing of shipment of bulk antisera products to our OEM customers may also move revenues from quarter to quarter. We also experience some seasonality in demand around holiday periods in both Europe and the United States. As a result of these factors, we expect to continue to see seasonality and quarter-to-quarter variations in our product sales.

The timing of product development fees included in other revenues is mostly dependent upon the achievement of pre-negotiated project and milestones.

Liquidity and Capital Resources

Since our commencement of operations in 2007, we have incurred net losses and negative cash flows from operations. As of March 31, 2016, we had an accumulated deficit of \$108.2 million. During the year ended March 31, 2016, we incurred a net loss of \$33.9 million and used \$47.0 million of cash for operating activities. During the year ended March 31, 2015, we had a net loss of \$59.1 million and used \$26.6 million of cash for operating activities. We incurred a net loss of \$10.2 million and used \$4.4 million of cash for operating activities during the year ended March 31, 2014. As described under results of operations, the increase in our use of cash during the years ended March 31, 2016 and March 31, 2015 was primarily attributable to our investment in the development of MosaiQ™ and increased corporate costs, including costs related to our transition to a public company.

Prior to our initial public offering, our principal source of funding had been investment in new share capital by our shareholders, which in the year ended March 31, 2014 amounted to \$3.1 million. In the year ended March 31, 2014, we also incurred net new

borrowings of \$11.6 million. On April 30, 2014, we completed our initial public offering and issued 5,000,000 units at \$8.00 per unit. We raised net proceeds of \$37.2 million after deducting underwriting discounts and commissions, while other costs of the offering amounted to \$3.6 million. Each unit comprised one ordinary share and one warrant and each warrant permitted the holder, prior to October 26, 2015, to subscribe for 0.8 of one new ordinary share at an exercise price equivalent to \$8.80 per underlying ordinary share. On October 26, 2015, the warrants expired and were delisted. Of the 5,000,000 warrants issued, 4,981,052 were exercised prior to the expiration date and 18,948 were cancelled on October 26, 2015. The exercise of the warrants resulted in the issuance of 3,984,823 ordinary shares and we received proceeds of \$35.1 million.

On November 25, 2014, we entered into subscription agreements with certain institutional and individual accredited investors for the private placement of 2,000,000 newly issued ordinary shares at a price of \$9.50 per share and 850,000 newly issued pre-funded warrants at a price of \$9.49 per warrant, amounting to an aggregate subscription price of approximately \$27.1 million. Each pre-funded warrant permits the holder to subscribe for one new ordinary share at an exercise price of \$0.01 per pre-funded warrant. The proceeds of this placement were \$27.1 million before costs and \$24.7 million net of costs.

On January 29, 2015, we entered into a subscription agreement with Ortho-Clinical Diagnostics Finco S.Á.R.L., an affiliate of Ortho, for the private placement of 444,445 newly issued ordinary shares at a price of \$22.50 per share and 666,665 newly issued 7% cumulative redeemable preference shares, of no par value, at a price of \$22.50 per share, for an aggregate subscription price of approximately \$25 million.

On August 3, 2015, we entered into an amended agreement with MidCap to expand our existing secured term loan facility from \$15.0 million to \$30.0 million. MidCap also agreed to make available, subject to certain conditions, additional credit facilities totaling \$20.0 million. The amended facility agreement with MidCap included a covenant to maintain cash balances above \$10 million.

On February 10, 2016 we completed a public offering of 4,444,445 of our ordinary shares at a price of \$9.00 per share. The net proceeds from this offering were \$36.8 million net of underwriting discounts and other offering expenses.

From our incorporation in 2012 to March 31, 2016, we have raised \$70.6 million of gross proceeds through the private placement of our ordinary and preference shares and we have raised \$115.1 million of gross proceeds from public offerings of our shares and warrants. As of March 31, 2016, we had cash and cash equivalents of \$44.1 million, which included \$0.3 million of cash held in a restricted account as part of the arrangements relating to the lease of our property in Eysins, Switzerland.

MidCap Term Loan Facility

On December 6, 2013, we entered into a secured term loan facility with MidCap Financial under which MidCap Financial advanced \$15.0 million to our U.S. subsidiary. The term loan bore interest at LIBOR + 6.7% (with a LIBOR floor of 2.00%). Interest was payable monthly in arrears and principal was repayable commencing on July 1, 2015 in 30 monthly installments. The loan was secured by all of our assets, including the equity of all our subsidiaries. Under the terms of the agreement, we granted MidCap Financial a warrant to purchase 200,000 C preference shares at an exercise price of \$3.00 per share. This was converted into a warrant to purchase 64,000 ordinary shares at \$9.38 per share immediately prior to the completion of our IPO in April 2014. We used \$3.0 million of the proceeds of this facility to repay the Haemonetics borrowings described below and the balance was available for general working capital purposes, including ongoing investment in MosaiQ™.

On August 3, 2015, we entered into an amended agreement with MidCap to expand its existing secured term loan facility from \$15 million to \$30 million. MidCap also agreed to make available additional credit facilities totaling \$20.0 million. As a result of the expansion of the facility, we received net proceeds in the aggregate amount of \$14.8 million.

The initial secured loan of \$30.0 million has a term of 48 months with interest only payments for the first 18 months and straight-line amortization of principal for the remaining 30 months. Interest on the outstanding balance of the term credit facility is payable monthly in arrears at an annual rate of one-month LIBOR plus 6.7% subject to a LIBOR floor of 2.0%. The loan is secured by all of our assets, including the equity of all of our subsidiaries.

The additional credit facilities, totaling \$20 million, are subject to us obtaining European CE Mark for the MosaiQ™ blood grouping consumable and the first commercial sale of the MosaiQ™ blood grouping consumable in the European Union.

Pursuant to the amended agreement, we issued to MidCap a warrant ("MidCap Warrant") to purchase 111,525 ordinary shares at an exercise price of \$16.14 per ordinary share. The MidCap Warrant is exercisable for a term of ten years and contains cashless exercise provisions and customary, share-based anti-dilution protection provisions. For additional information regarding the MidCap Warrant, see "Item 5. Recent Sale of Unregistered Securities."

The terms of the secured term loan facility contain various affirmative and negative covenants. In particular, we are not permitted to allow net product revenue over a 12-month period to be lower than a range of minimum thresholds specified in the agreement. The testing dates are on the 15th of each month and the testing periods are the twelve full months ending one full calendar month preceding each testing date. In addition, we are required to maintain unrestricted cash and cash equivalents in an amount not less than \$10 million as of the last day of each calendar month.

Haemonetics Loan Notes

In 2010, we borrowed \$3.0 million from Haemonetics, Inc., a healthcare company providing blood management solutions, by issuing loan notes in the same amount. Our borrowings from Haemonetics bore interest at a rate of 7.5% per annum calculated and payable quarterly in arrears, and were redeemable in March of 2017. On December 9, 2013, we repaid our Haemonetics borrowings in full with the proceeds of our initial MidCap Financial term loan agreement described above.

Cash Flows for the Years Ended March 31, 2016 and 2015

Operating activities

Net cash used in operating activities was \$47.0 million during the year ended March 31, 2016, which included net losses of \$33.9 million and non-cash items of \$8.8 million. Non-cash items were depreciation and amortization expense of \$2.9 million, share-based compensation expense of \$2.0 million, amortization of deferred debt issue costs of \$1.5 million and accrued preference share dividends of \$1.1 million, offset by a change in the fair value of the liability in respect of share warrants of \$15.9 million and amortization of lease incentives of \$0.4 million. We also experienced a net cash outflow of \$4.3 million from changes in operating assets and liabilities during the period, consisting primarily of an \$8.1 million increase in inventories and a \$0.5 million increase in accounts receivable, offset by a \$2.6 million decrease in other assets and a \$1.8 million increase in accounts payable and accrued liabilities.

Net cash used in operating activities was \$26.6 million during the year ended March 31, 2015, which included net losses of \$59.1 million and non-cash items of \$26.3 million. Non-cash items were depreciation and amortization expense of \$1.7 million, share-based compensation expense of \$1.1 million, amortization of deferred debt issue costs of \$0.8 million, accrued preference share dividends of \$0.2 million and a change in the fair value of the liability in respect of share warrants of \$23.0 million, offset by amortization of lease incentives of \$0.4 million. We also experienced a net cash inflow of \$6.2 million from changes in operating assets and liabilities during the period, consisting primarily of a \$7.4 million increase in accounts payable and accrued liabilities, a \$0.8 million increase in accrued compensation and benefits and a \$0.4 million reduction in accounts receivable, offset by a \$0.6 million increase in inventories and a \$1.8 million increase in other assets.

Investing activities

Net cash used in investing activities was \$29.0 million and \$24.0 million for the years ended March 31, 2016 and 2015, respectively. Purchases of property and equipment in the year ended March 31, 2016 were \$28.9 million and included \$24.5 million related to the MosaiQ™ project and \$4.4 million related to our conventional reagent business. We also invested \$0.1 million on new product licenses within our conventional reagent operations. Purchases of property and equipment in the year ended March 31, 2015 included \$23.4 million related to the MosaiQ™ project and \$0.5 million related to our conventional reagent business. We also invested \$0.2 million on new product licenses within our conventional reagent operations in the year ended March 31, 2015.

Financing activities

Net cash provided by financing activities was \$85.6 million during the year ended March 31, 2016, consisting primarily of net proceeds of \$36.8 million from the February 2016 public offering of ordinary shares and net proceeds of \$34.5 million from the exercise of warrants issued at the time of our initial public offering and incentive share options. We also received \$14.3 million from the expansion of our secured credit facility with MidCap in August 2015.

Net cash provided by financing activities was \$85.1 million during the year ended March 31, 2015, consisting primarily of net proceeds of \$34.3 million from our initial public offering, net proceeds of \$24.7 million from the November 2014 private placement of ordinary shares and pre-funded warrants, net proceeds of \$25.0 million from the January 2015 private placement of ordinary shares and preference shares, \$0.8 million of proceeds from the exercise of options and warrants and \$0.2 million of net capital lease receipts.

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Cash Flows for the Years Ended March 31, 2015 and 2014

Operating activities

Net cash used in operating activities was \$26.6 million during the year ended March 31, 2015, which included net losses of \$59.1 million and non-cash items of \$26.3 million. Non-cash items were depreciation and amortization expense of \$1.7 million, share-based compensation expense of \$1.1 million, amortization of deferred debt issue costs of \$0.8 million, accrued preference share dividends of \$0.2 million and a change in the fair value of the liability in respect of share warrants of \$23.0 million, offset by amortization of lease incentives of \$0.4 million. We also experienced a net cash inflow of \$6.2 million from changes in operating assets and liabilities during the period, consisting primarily of a \$7.4 million increase in accounts payable and accrued liabilities, a \$0.8 million increase in accrued compensation and benefits and a \$0.4 million reduction in accounts receivable, offset by a \$0.6 million increase in inventories and a \$1.8 million increase in other assets.

Net cash used in operating activities was \$4.4 million during the year ended March 31, 2014, which included net losses of \$10.2 million and non-cash items of \$2.0 million. Non-cash items were depreciation and amortization expense of \$0.6 million, share-based compensation expense of \$0.9 million and amortization of deferred debt issue costs of \$0.5 million. We also experienced a net cash inflow of \$3.8 million from changes in operating assets and liabilities during the period, consisting primarily of a \$5.1 million increase in accounts payable and accrued liabilities, a \$0.9 million increase in accrued compensation and benefits and the receipt of a lease incentive of \$2.9 million, offset by a \$0.7 million increase in accounts receivable, a \$0.9 million increase in inventories and a \$3.5 million increase in other assets.

Investing activities

Net cash used in investing activities was \$24.0 million and \$7.1 million for the years ended March 31, 2015 and 2014, respectively. Purchases of property and equipment in the year ended March 31, 2015 included \$23.4 million related to the MosaiQ™ project and \$0.5 million related to our conventional reagent business. We also invested \$0.2 million on new product licenses within our conventional reagent operations in the year ended March 31, 2015. Purchases of property and equipment in the year ended March 31, 2014 included \$6.8 million related to the MosaiQ™ project and \$0.4 million related to our conventional reagent business.

Financing activities

Net cash provided by financing activities was \$85.1 million during the year ended March 31, 2015, consisting primarily of net proceeds of \$34.3 million from our initial public offering, net proceeds of \$24.7 million from the November 2014 private placement of ordinary shares and pre-funded warrants, net proceeds of \$25.0 million from the January 2015 private placement of ordinary shares and preference shares, \$0.8 million of proceeds from the exercise of options and warrants and \$0.2 million of net capital lease receipts.

Net cash provided by financing activities was \$14.6 million during the year ended March 31, 2014, consisting primarily of share issuance proceeds of \$3.1 million and net borrowings of \$11.6 million, which was offset by \$166,000 of capital lease payments.

Operating and Capital Expenditure Requirements

We have not achieved profitability on an annual basis since we commenced operations in 2007 and we expect to incur net losses for at least the next fiscal year. We expect our operating expenses to increase during the year ended March 31, 2017, as we continue to invest in MosaiQ™, grow our customer base, expand our marketing and distribution

channels, hire additional employees and invest in other product development opportunities.

As of March 31, 2016, we had cash and cash equivalents of \$44.1 million, including \$0.3 million of cash held in a restricted account as part of the arrangements relating to the lease of our property in Eysins, Switzerland.

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

- our progress in developing and commercializing MosaiQ™ and the cost required to complete development, obtain regulatory approvals and complete our manufacturing scale up;

- Ortho's progress in commercializing MosaiQ™ for the patient testing market;

- our ability to manufacture and sell our conventional reagent products, including the costs and timing of further expansion of our sales and marketing efforts;

- our ability to collect our accounts receivable;

- our ability to generate cash from operations;

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any acquisition of businesses or technologies that we may undertake; and our ability to penetrate our existing market and new markets.

We expect to fund our operations in the near term, including the continued development of MosaiQ™ to commercialization, from a combination of funding sources, including through the use of existing cash balances, asset-based financing and the issuance of new equity and debt. We are confident in the availability of these funding sources. However, there can be no assurance that we will be able to obtain adequate financing when necessary and the terms of any financings may not be advantageous to us and may result in dilution to our shareholders.

Contractual Obligations

We have contractual obligations for non-cancelable facilities leases, our credit facilities, equipment leases and purchase commitments. The following table sets forth a summary of our contractual obligations as of March 31, 2016.

	Total	Payment by period			
		Less than 1 year	1 to 3 years	3 to 5 years	After 5 years
Contractual Obligations					
MidCap Financial long term debt	\$30,000	\$1,000	\$24,000	\$5,000	\$ —
Interest on MidCap Financial debt	6,897	2,603	2,871	1,423	—
7% Cumulative Redeemable Preference					
Shares (1)	15,000	—	15,000	—	—
Dividends on 7% Cumulative					
Redeemable Preference Shares (1)	4,200	—	4,200	—	—
Operating and capital leases	9,500	2,754	5,311	1,435	—
STRATEC Biomedical development					
agreement (2)	4,054	4,054	—	—	—
STRATEC Biomedical manufacturing					
agreement (3)	58,778	—	22,850	35,928	—
SCHOTT supply agreement (4)	3,283	3,283	—	—	—
MW High Tech Projects construction					
contract (5)	26,059	21,452	4,607	—	—
Other	7,264	6,907	357	—	—
Total contractual obligations	\$165,035	\$42,053	\$79,196	\$43,786	\$ —

(1) The 7% Cumulative Redeemable Preference Shares are redeemable at the option of the shareholders on a date not before January 29, 2019, which can be extended at our option in one year increments until January 29, 2025. We can pay dividends on the 7% Cumulative Redeemable Preference Shares at any time, but are not obligated to do so until redemption.

(2) We have entered into a development agreement with STRATEC Biomedical AG, or STRATEC, in connection with the development of the MosaiQ™ instrument. STRATEC's fees under this agreement will total in aggregate

\$14.9 million (€13.1 million) using March 31, 2016 exchange rates, of which \$10.8 million (€9.5 million) of expense was incurred prior to March 31, 2016. For a description of our development agreement with STRATEC, see “Business—MosaiQTM Manufacturing and Supply—STRATEC Biomedical AG”.

- (3) We have entered into a manufacturing agreement with STRATEC in connection with the supply of MosaiQTM instruments over a six year period starting after completion of the sixth development milestone. The total purchase obligation under this agreement is \$58.8 million (€51.8 million) using March 31, 2016 exchange rates.
- (4) We have entered into a supply agreement with SCHOTT Technical Glass Solutions GmbH, or SCHOTT, pursuant to which we will purchase minimum quantities of coated glass in connection with the development of the MosaiQTM consumable through April 2017. The total purchase obligation under this agreement is \$10.7 million (€9.4 million) using March 31, 2016 exchange rates, of which \$7.4 million (€6.5 million) was paid prior to March 31, 2016. In the event we have not purchased the required quantities during any calendar year, we are obligated to pay SCHOTT a minimum commitment, which in aggregate amounts to \$8.3 million (€7.3 million), using March 31, 2016 exchange rates. The payments of \$7.4 million (€6.5 million) made prior to March 31, 2016 count towards this minimum commitment. For a description of our supply agreement with SCHOTT, see “Business—MosaiQTM Manufacturing and Supply—SCHOTT Technical Glass Solutions GmbH”.
- (5) We have entered into a contract with MW High Tech Products UK Limited for the construction of a new manufacturing facility for our conventional reagents business near Edinburgh, Scotland. This contract can be terminated by us at any time upon payment of the construction costs accrued to the date of termination.

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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, 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

Revenue is recognized in accordance with Accounting Standards Codification, or ASC, Topic No. 605, "Revenue Recognition," when the following four basic criteria have been met: (1) persuasive evidence of an arrangement exists; (2) delivery has occurred or services are rendered; (3) the fee is fixed or determinable; and (4) collectability is reasonably assured. For product sales, the application of this policy results in sales revenue being recorded at the point of delivery of product to the customer.

We also earn revenue from the provision of development services to a small number of OEM customers. These development service contracts are reviewed individually to ensure that our revenue recognition is in accordance with applicable accounting standards, including ASC Topic No. 605. In the last eighteen months, our product development revenues have been commensurate with achieving milestones specified in the respective development agreements relating to those products. These milestones may include the approval of new products by the European or U.S. regulatory authorities, which are not within our control. While there can be no assurance that we will earn product development revenues when milestones are achieved, the nature of the milestones have been such that they effectively represent full completion of a particular part of a development program. As a result, we typically fully recognize milestone-related revenues as the milestones are achieved in accordance with applicable accounting standards.

Under certain development contracts, we also manufacture and supply the customer with finished products once it has been approved for use by relevant regulatory agencies. These agreements reflect both arrangements for product development and the sales prices and other contractual terms for subsequent supply of the product to the customer. Under these development contracts, we view the development service revenue as distinct from subsequent product sales revenue, and we recognize each separately as described above.

Accounts receivable consist primarily of amounts due from OEM customers, hospitals, donor testing laboratories, and distributors. Accounts receivable are reported net of an allowance for uncollectible accounts, which we also refer to as doubtful accounts. The allowance for doubtful accounts represents a reserve for estimated losses resulting from our inability to collect amounts due from our customers. Direct sales, where we may make many low value sales to a large number of customers, represents a larger risk of doubtful accounts, as opposed to OEM customer sales consisting primarily of a small number of well established businesses with whom we have a long trading history. The collectability of our trade receivables balances is regularly evaluated based on a combination of factors such as the ageing profile of our receivables, past history with our customers, changes in customer payment patterns, customer credit-worthiness and any other relevant factors. Based on these assessments, we adjust the reserve for doubtful accounts recorded in our financial statements.

Inventories

We record inventories at the lower of cost (first-in, first-out basis) or market (net realizable value), net of reserves. We record adjustments to inventory based upon historic usage, expected future demand and shelf life of the products held in inventory. We also calculate our inventory value based on the standard cost of each product. This approach requires us to analyze variances arising in the production process to determine whether they reflect part of the normal cost of production, and should therefore be reflected as inventory value, or whether they are a period cost and should thus not be included in inventory.

Intangible assets

The intangible assets included in our financial statements include intangible assets identified as at the time of the acquisition of the business of Alba Bioscience on August 31, 2007. At the time of this acquisition, we identified intangible assets related to customer relationships, master cell lines and certain other items, which include domain names and product trademarks. The customer

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relationships have been amortized over a five-year period, which resulted in them becoming fully amortized at August 31, 2012. The other items were amortized over a seven-year period from August 31, 2007.

The intangible assets related to master cell lines reflect the know-how and market recognition associated with the cell lines, which are used as the source material of certain of our products. These cell lines are maintained by us and have an indefinite life. We have nevertheless decided to amortize the intangible assets over a forty-year period to reflect the possibility of market changes or other events resulting in the lines becoming technically obsolete at some future date. In the event that any of the lines cease to be used, we would record additional amortization at that point.

We also include in intangible assets the costs of obtaining product licenses for our products. These include external costs such as regulatory agency fees associated with the approval and bringing to market of our products once the development is complete. We amortize these over an expected product life of eight years, although if any such product ceased to be produced, we would record additional amortization at that point.

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 NOLs and research and development credit carry forwards. 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 March 31, 2016, 2015 or 2014.

Stock compensation expense

Stock compensation expense is measured at the grant date based on the fair value of the award and is recognized as an expense in the income statement over the vesting period of the award. The calculation of the stock compensation expense is sensitive to the fair value of the underlying ordinary shares. The fair value of option awards and multi-year performance based restricted share units or MRSUs at the grant date is calculated using the Black-Scholes model or other valuation models, which use a number of assumptions to determine the fair value. Details of the assumptions used are set out in the notes to the financial statements included in this Annual Report.

Defined Benefit Pension Obligations

We account for the pension obligations of our Swiss subsidiary as a defined benefit plans under Accounting Standards Codification Topic, 715 Compensation – Retirement Benefits or ASC 715. This requires that an actuarial valuation be performed to determine the funded status of the pension arrangements. The actuarial valuation is based on a number of assumptions, details of which are set out in the notes to the financial statements included in this Annual Report.

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

We have considered recent accounting pronouncements and determined that they are either not applicable to our business or that no material effect is expected on the consolidated financial statements as a result of future adoption.

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JOBS Act

Under 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 have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, we will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

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

Interest rate sensitivity

We are exposed to market risk related to changes in interest rates as it impacts our interest income and expense.

Cash and cash equivalents. At March 31, 2016, we had cash and cash equivalents of \$44.1 million. Our exposure to market risk includes interest income sensitivity, which is impacted by changes in the general level of U.S. and European interest rates. Our cash and cash equivalents are held in interest-bearing savings accounts and bank accounts. We do not enter into investments for trading or speculative purposes. Due to the current levels of interest rates, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our holdings, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

Term loan facility. We currently have term debt of \$30.0 million drawn under a term loan facility with MidCap Financial Trust. The term loan carries a variable interest rate of 6.7% above LIBOR, with a LIBOR floor of 2.00%. If there is a rise in LIBOR interest rates above 2.00%, our debt service obligation would increase even though the amount borrowed remained the same, which would affect our results of operations, financial condition and liquidity. Assuming no change in our debt obligations from the amount drawn down under the term loan, a hypothetical one percentage point change in underlying variable rates would not currently change our annual interest expense and cash flow from operations.

Foreign currency exchange risk

The main currencies that we use for our trading operations are the U.S. Dollar, the Pound Sterling, the Swiss Franc and to a lesser extent, the Euro. Our meaningful cash balances are held in a mixture of U.S. Dollars, Euros, Pounds Sterling and Swiss Francs. These cash balances may not be the same as the functional currencies of the Quotient entities in which they are held and as a result, exchange rate fluctuations may result in foreign exchange gains and losses on our income statement.

We are subject to market risks arising from changes in foreign currency exchange rates between the U.S. Dollar and the Pound Sterling and the U.S. Dollar and the Swiss Franc. Accordingly, fluctuations in the U.S. Dollar versus Pounds Sterling and U.S. Dollar versus the Swiss Franc exchange rate give rise to exchange gains and losses. These gains and losses arise from the conversion of U.S. Dollars and Euros to Pounds Sterling and the retranslation of cash, accounts receivable, intercompany indebtedness and other asset and liability balances. Based on our assets and

liabilities held in Pounds Sterling at March 31, 2016, we estimate that a 5% strengthening of the Pound Sterling against the U.S. Dollar would give rise to a gain of approximately \$1.4 million and a 5% weakening of the Pound Sterling against the U.S. Dollar would give rise to loss of approximately \$1.4 million. Based on our assets and liabilities held in Swiss Francs at March 31, 2016, we estimate that a 5% strengthening of the Swiss Franc against the U.S. Dollar would give rise to a gain of approximately \$1.4 million and a 5% weakening of the Swiss Franc against the U.S. Dollar would give rise to loss of approximately \$1.4 million.

A significant proportion of our revenues are earned in U.S. Dollars, but the costs of our conventional reagent manufacturing operations are payable mainly in Pounds Sterling. We therefore closely monitor the results of our UK operations to address this difference. During the year ended March 31, 2016, the net operating expenses arising in Pounds Sterling from our UK conventional reagent manufacturing operations amounted to \$14.0 million. This expenditure is offset by revenues arising in U.S. Dollars and other currencies. We have entered into forward contracts to hedge against the effects of fluctuations in the U.S. Dollar versus the Pounds Sterling exchange rate. The principal value of the hedges related to the results of fiscal year 2017 is \$4.5 million and, based on this, a hypothetical instantaneous 5% strengthening of the Pound Sterling against the U.S. Dollar would reduce our net income by \$0.5 million in the year ending March 31, 2017 after taking account of the shelter provided by our existing hedging arrangements through December 2016. Similarly, a hypothetical instantaneous 5% weakening of the Pound Sterling against the U.S. Dollar would increase group net income by \$0.5 million over the same period.

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We do not use financial instruments for trading or other speculative purposes.

Our management does not believe that inflation in past years has had a significant impact on our results from operations. In the event inflation affects our costs in the future, we will offset the effect of inflation and maintain appropriate margins through increased selling prices.

Item 8. Financial Statements and Supplementary Data

The quarterly financial data required by this item may be found in “Management’s Discussion and Analysis of Financial Condition and Results of Operations—Quarterly Results of Operations.”

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Report of Independent Registered Public Accounting Firm

The Board of Directors and Shareholders of Quotient Limited

We have audited the accompanying consolidated balance sheets of Quotient Limited as of March 31, 2016 and 2015, and the related consolidated statements of comprehensive loss, redeemable convertible preference shares and changes in shareholders' deficit, and cash flows for each of the three years in the period ended March 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 Quotient Limited at March 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 March 31, 2016, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has recurring losses from operations and planned expenditure exceeding available funding that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Ernst & Young LLP

Belfast, United Kingdom

May 31, 2016

QUOTIENT LIMITED

CONSOLIDATED BALANCE SHEETS

(Expressed in thousands of U.S. Dollars — except for share data and per share data)

	March March 31,	March 31,
	2016	2015
ASSETS		
Current assets:		
Cash and cash equivalents	\$44,100	\$37,525
Trade accounts receivable, net	2,269	1,808
Inventories	12,584	4,608
Prepaid expenses and other current assets	2,780	5,580
Total current assets	61,733	49,521
Property and equipment, net	57,115	29,733
Intangible assets, net	902	950
Total assets	\$119,750	\$80,204
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$7,286	\$7,238
Accrued compensation and benefits	3,294	2,565
Accrued expenses and other current liabilities	9,180	8,787
Financial liability in respect of share warrants	—	31,011
Current portion of long-term debt	1,000	4,500
Current portion of lease incentive	439	435
Current portion of capital lease obligation	152	239
Total current liabilities	21,351	54,775
Long-term debt, less current portion	27,910	9,853
Lease incentive, less current portion	1,316	1,740
Capital lease obligation, less current portion	1,723	276
Defined benefit pension plan obligation	4,502	—
7% Cumulative redeemable preference shares	16,225	15,175
Total liabilities	73,027	81,819
Commitments and contingencies	—	—
Shareholders' equity (deficit)		
Ordinary shares (nil par value) 25,408,950 and 17,020,574 issued and outstanding		
at March 31, 2016 and March 31, 2015 respectively;	155,914	84,525
Additional paid in (distribution in excess of) capital	11,664	(6,684)
Accumulated other comprehensive loss	(12,623)	(5,102)
Accumulated deficit	(108,232)	(74,354)
Total shareholders' equity (deficit)	46,723	(1,615)
Total liabilities and shareholders' equity (deficit)	\$119,750	\$80,204

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

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

(Expressed in thousands of U.S. Dollars — except for share data and per share data)

	Year ended March 31,		
	2016	2015	2014
Revenue:			
Product sales	\$ 18,022	\$ 17,658	\$ 16,987
Other revenues	500	750	2,768
Total revenue	18,522	18,408	19,755
Cost of revenue	(9,658)	(9,763)	(8,406)
Gross profit	8,864	8,645	11,349
Operating expenses:			
Sales and marketing	(3,073)	(2,750)	(2,705)
Research and development, net of government grants	(28,781)	(19,216)	(8,066)
General and administrative expense:			
Compensation expense in respect of share			
options and management equity incentives	(2,004)	(1,138)	(933)
Other general and administrative expenses	(24,094)	(15,255)	(8,537)
Total general and administrative expense	(26,098)	(16,393)	(9,470)
Total operating expense	(57,952)	(38,359)	(20,241)
Operating loss	(49,088)	(29,714)	(8,892)
Other income (expense)			
Interest expense, net	(4,151)	(2,315)	(1,076)
Change in financial liability for share warrants	15,857	(22,966)	—
Other, net	3,504	(4,064)	(197)
Other income (expense), net	15,210	(29,345)	(1,273)
Loss before income taxes	(33,878)	(59,059)	(10,165)
Provision for income taxes	—	—	—
Net loss	\$(33,878)	\$(59,059)	\$(10,165)
Other comprehensive income (loss):			
Change in fair value of effective portion of			
foreign currency cash flow hedges	\$9	\$(293)	\$94
Foreign currency gain (loss)	(3,028)	(5,114)	397
Provision for pension benefit obligation	(4,502)	—	—
Other comprehensive income (loss)	(7,521)	(5,407)	491
Comprehensive loss	\$(41,399)	\$(64,466)	\$(9,674)
Net loss available to ordinary shareholders			
- basic and diluted	\$(33,878)	\$(59,059)	\$(10,165)
Loss per share - basic and diluted	\$(1.73)	\$(4.00)	\$(54.41)
Weighted-average shares outstanding - basic and			
diluted	19,558,152	14,773,386	186,817

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

CONSOLIDATED STATEMENTS OF REDEEMABLE CONVERTIBLE PREFERENCE SHARES AND
CHANGES IN SHAREHOLDERS' EQUITY

(Expressed in thousands of U.S. Dollars — except for share data)

	Redeemable		Convertible		Deferred shares	Additional paid in (Distribution in excess of capital)	Other Comprehensive Loss	Accumulated Deficit
	Preference Shares	Amount	Ordinary shares	Amount				
	Shares		Shares	Amount				
2013	27,160,855	\$28,021	75,914	\$—	206,184	\$—	\$(17,745)	\$(5,130)
Shares upon exercise of warrants	142,506	150	—	—	—	19	—	—
Shares, net of issue costs of \$195	929,167	2,592	60,044	247	—	—	—	—
of deferred shares	—	—	206,184	—	(206,184)	—	—	—
	—	—	—	—	—	—	—	(10,165)
The fair value of the effective								
of foreign currency								
Hedges	—	—	—	—	—	—	94	—
currency translation loss	—	—	—	—	—	—	397	—
Comprehensive income	—	—	—	—	—	—	491	—
and compensation	—	—	—	—	—	933	—	—
2014	28,232,528	\$30,763	342,142	\$247	\$—	\$—	\$(16,793)	\$305
of shares	(28,232,528)	(30,763)	9,034,405	30,866	—	421	—	—
Shares, net of issue costs								
7	—	—	7,444,445	52,561	—	—	—	—
Unfunded warrants	—	—	—	—	—	8,067	—	—
Shares upon exercise of								
share options	—	—	137,478	304	—	—	—	—
Shares upon exercise of warrants	—	—	62,104	547	—	483	—	—
	—	—	—	—	—	—	—	(59,059)
The fair value of the effective								
of foreign currency cash								
Hedges	—	—	—	—	—	—	(293)	—
currency translation loss	—	—	—	—	—	—	(5,114)	—
Comprehensive loss	—	—	—	—	—	—	(5,407)	—
and compensation	—	—	—	—	—	1,138	—	—
2015	—	\$—	17,020,574	\$84,525	\$—	\$—	\$(6,684)	\$(5,102)
Shares, net of issue costs of \$3,165	—	—	4,444,445	36,835	—	—	—	—
Shares upon exercise of								
share options	—	—	21,212	41	—	—	—	—

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Shares upon exercise of warrants	—	—	3,922,719	34,513	—	—	15,154	—	—
Warrants	—	—	—	—	—	—	1,190	—	—
	—	—	—	—	—	—	—	—	(33,878)
The fair value of the effective									
of foreign currency cash									
Changes	—	—	—	—	—	—	—	9	—
Foreign currency translation loss	—	—	—	—	—	—	—	(3,028)	—
For pension benefit obligation	—	—	—	—	—	—	—	(4,502)	—
Comprehensive loss	—	—	—	—	—	—	—	(7,521)	—
And compensation	—	—	—	—	—	—	2,004	—	—
2016	—	\$—	25,408,950	\$155,914	\$—	\$—	\$11,664	\$(12,623)	\$(108,232)

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

CONSOLIDATED STATEMENTS OF CASH FLOWS

(Expressed in thousands of U.S. Dollars)

	Year ended March 31,		
	2016	2015	2014
OPERATING ACTIVITIES:			
Net loss	\$(33,878)	\$(59,059)	\$(10,165)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation, amortization and loss on disposal of fixed assets	2,945	1,676	622
Share-based compensation	2,004	1,138	933
Amortization of lease incentive	(434)	(443)	—
Amortization of deferred debt issue costs	1,472	776	464
Accrued preference share dividends	1,050	175	—
Change in financial liability for share warrants	(15,857)	22,966	—
Net change in assets and liabilities:			
Trade accounts receivable, net	(519)	362	(748)
Inventories	(8,126)	(552)	(897)
Accounts payable and accrued liabilities	955	7,358	5,100
Accrued compensation and benefits	812	772	874
Lease incentive	—	—	2,907
Other assets	2,603	(1,760)	(3,470)
Net cash used in operating activities	(46,973)	(26,591)	(4,380)
INVESTING ACTIVITIES:			
Purchase of property and equipment	(28,906)	(23,854)	(7,226)
Refund (purchase) of intangible assets	(71)	(188)	94
Net cash used in investing activities	(28,977)	(24,042)	(7,132)
FINANCING ACTIVITIES:			
Proceeds from (repayment of) finance leases	(39)	195	(166)
Proceeds from drawdown of new debt	15,000	—	15,000
Repayment of debt	—	—	(3,000)
Debt issue costs	(703)	—	(372)
Proceeds from issuance of preference shares	—	15,000	2,885
Proceeds from issuance of ordinary shares	71,390	69,879	247
Net cash generated from financing activities	85,648	85,074	14,594
Effect of exchange rate fluctuations on cash and cash equivalents	(3,123)	(4,108)	(109)
Change in cash and cash equivalents	6,575	30,333	2,973
Beginning cash and cash equivalents	37,525	7,192	4,219
Ending cash and cash equivalents	\$44,100	\$37,525	\$7,192
Supplemental cash flow disclosures:			
Income taxes paid	\$—	\$—	\$—
Interest paid	\$2,164	\$1,364	\$637

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

(Expressed in thousands of U.S. Dollars — except for share data and per share data, unless otherwise stated)

Note 1. Organization and Summary of Significant Accounting Policies

Organization and Business

On January 18, 2012, Quotient Limited (“the Company”) was incorporated in accordance with the Companies (Jersey) Law. On February 16, 2012, in consideration for the issue of 14,023,552 A Preference shares to Quotient Biodiagnostics Group Limited (“QBDG” or “the Predecessor”) Quotient Limited acquired the entire issued share capital of Alba Bioscience Limited (“Alba”), Quotient Biodiagnostics, Inc. (“QBDI”) and QBD (QSIP) Limited (“QSIP”) from QBDG.

On February 16, 2012, Quotient Limited also: (i) issued 10,640,664 B Preference shares to third-party investors; (ii) issued 56,936 A Ordinary shares, 18,978 A Deferred shares, 37,957 B Deferred shares and 168,227 C Deferred shares to the holders of equivalent shares in QBDG; (iii) repurchased 1,553,598 A Preference shares; and (iv) purchased certain intellectual property rights relating to MosaiQ™ from QBDG.

The acquisition of Alba, QBDI and QSIP by Quotient Limited is a combination of entities under common control as these entities were all controlled by QBDG prior to their acquisition by Quotient Limited. It recognized the assets and liabilities of Alba, QBDI and QSIP at their carrying amounts in the financial statements of those companies. The excess of the subscription value of A Preference shares issued to QBDG over the carrying amounts of transferred net assets was treated as an equity transaction and was recorded as distribution in excess of capital in the Consolidated Statements of Redeemable Convertible Preference Shares and Changes in Shareholders’ Deficit. Quotient Limited is a continuation of QBDG and its subsidiaries, accordingly, the consolidated financial statements include the assets, liabilities and results of operations of the subsidiaries transferred since their inception. The transfer of intellectual property rights from QBDG to QSIP is accounted for as a transaction between entities under common control. All of the amounts paid by QSIP in exchange for the asset is shown as a payment to predecessor shareholder in the statements of cash flows.

The principal activity of Quotient Limited and its subsidiaries (the “Group” and or the “Company”) is the development, manufacture and sale of products for the global transfusion diagnostics market. Products manufactured by the Group are sold to hospitals, blood banking operations and other diagnostics companies worldwide.

Quotient Limited completed an initial public offering for its ordinary shares on April 30, 2014 pursuant to which it issued 5,000,000 units each consisting of one ordinary share, no par value and one warrant to purchase 0.8 of one ordinary share at an exercise price of \$8.80 per whole ordinary share, raising \$40 million of new equity share capital before issuing expenses.

Immediately prior to its initial public offering, the Company’s outstanding preference shares, A ordinary shares and B ordinary shares were converted to ordinary shares and the ordinary shares then outstanding were consolidated into 32 new ordinary shares for each 100 existing ordinary shares. The number of ordinary and deferred shares and number of options and warrants to acquire ordinary shares are presented in these financial statements on the basis of the number after this consolidation. The number of preference shares are shown on the basis of the number before this consolidation.

On November 25, 2014, the Company entered into subscription agreements with certain institutional and individual accredited investors for the private placement of 2,000,000 newly issued ordinary shares at a price of \$9.50 per share and 850,000 newly issued pre-funded warrants at a price of \$9.49 per warrant, amounting to an aggregate subscription price of approximately \$27.1 million. Each pre-funded warrant permits the holder to subscribe for one new ordinary share at an exercise price of \$0.01 per pre-funded warrant. The proceeds of this placement were \$27.1 million before costs and \$24.7 million net of costs.

On January 29, 2015, the Company entered into a distribution and supply agreement with Ortho-Clinical Diagnostics, Inc. (“Ortho”) for an initial term of 20 years. Pursuant to this agreement, Ortho will exclusively commercialize MosaiQ™ for the global patient testing market, as well as the donor testing market in territories other than those in which the Company will commercialize MosaiQ™. Ortho has agreed to pay the Company one time payments upon the achievement of certain milestones totaling in the aggregate \$59 million and reimburse the Company for the cost of goods sold incurred for MosaiQ™ instruments and associated replacement parts sold to Ortho, as well as the cost of ancillary products sold to Ortho (other than quality control products), plus 10% of such ancillary product costs. A transfer price mechanism for MosaiQ™ consumables sold to Ortho has also been established, which will increase based on agreed-upon revenue milestones. We also entered into a subscription agreement with Ortho-Clinical Diagnostics Finco S.Á.R.L., an affiliate of Ortho, for the private placement of 444,445 newly issued ordinary shares at a price of \$22.50 per share and 666,665 newly issued 7% cumulative redeemable preference shares, of no par value, of the Company at a price of \$22.50 per share, for an aggregate subscription price of approximately \$25 million.

On August 3, 2015, the Company entered into an amended agreement with MidCap Financial Trust to expand its existing secured term loan facility from \$15.0 million to \$30.0 million. MidCap Financial Trust also agreed to make available, subject to certain conditions, additional credit facilities totaling \$20.0 million. The amended facility agreement with MidCap Financial Trust included a covenant to maintain cash balances above \$10 million.

On October 26, 2015, the warrants issued at the time of the Company's initial public offering expired. Of the 5,000,000 issued warrants, 4,981,052 were exercised prior to the expiration date and 18,948 were cancelled on October 26, 2015. The exercise of the warrants resulted in the issuance of 3,984,823 ordinary shares and proceeds of \$35.1 million being received by the Company.

On February 10, 2016, the Company completed a public offering of 4,444,445 of its ordinary shares at a price of \$9.00 per share. The net proceeds from this offering were \$36.8 million net of underwriting discounts and other offering expenses.

The Company has incurred net losses and negative cash flows from operations in each year since it commenced operations in 2007 and had an accumulated deficit of \$108.2 million as of March 31, 2016. At March 31, 2016 the Company had cash holdings of \$44.1 million and had covenants in place with lenders to maintain cash holdings above \$10 million. The Company has expenditure plans over the next twelve months that exceed its current cash holdings, raising substantial doubt about its ability to continue as a going concern. The Company expects to fund its operations in the near term, including the continued development of MosaiQ™ to commercialization, from a combination of funding sources, including through the use of existing cash balances, asset-based financing and the issuance of new equity or debt. The Company's Directors are confident in the availability of these funding sources and accordingly have prepared the financial statements on the going concern basis. However, there can be no assurance the Company will be able to obtain adequate financing when necessary and the terms of any financings may not be advantageous to the Company and may result in dilution to its shareholders.

Principles of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiaries after elimination of intercompany transactions and balances. All gains and losses realized from foreign currency transactions denominated in currencies other than the foreign subsidiary's functional currency are included in foreign currency exchange gain (loss) as part of other income or expenses in the Consolidated Statements of Comprehensive Loss. Adjustments resulting from translating the financial statements of all foreign subsidiaries into U.S. dollars are reported as a separate component of accumulated other comprehensive income (loss) and changes in shareholders' deficit. The assets and liabilities of the Company's foreign subsidiaries are translated from their respective functional currencies into U.S. dollars at the rates in effect at the balance sheet date, and revenue and expense amounts are translated at rates approximating the weighted average rates during the period.

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from these estimates.

Fair Value of Financial Instruments

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company's valuation techniques used to measure fair value

maximized the use of observable inputs and minimized the use of unobservable inputs. The fair value hierarchy is based on the following three levels of inputs:

Level 1—Quoted prices in active markets for identical assets or liabilities.

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

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

See Note 4, “Fair Value Measurements,” for information and related disclosures regarding our fair value measurements.

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Cash and cash equivalents

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. As of March 31, 2016 and 2015, all cash and cash equivalents comprised cash balances held with the banks used by the company and its subsidiaries. At March 31, 2016 and March 31, 2015, the Company held \$317 and \$314 respectively in a restricted account as security for the property rental obligations of the Company's Swiss subsidiary.

Trade accounts receivable

Trade accounts receivable are recorded at the invoiced amount and are not interest bearing. The Company maintains an allowance for doubtful accounts to reserve for potentially uncollectible trade receivables. Additions to the allowance for doubtful accounts are recorded as general and administrative expenses. The Company reviews its trade receivables to identify specific customers with known disputes or collectability issues. In addition, the Company maintains an allowance for all other receivables not included in the specific reserve by applying specific rates of projected uncollectible receivables to the various aging categories. In determining these percentages, the Company analyzes its historical collection experience, customer credit-worthiness, current economic trends and changes in customer payment terms. The allowance for doubtful accounts at March 31, 2016 and 2015 was \$126 and \$150, respectively.

Concentration of Credit Risks and Other Uncertainties

The carrying amounts for financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their short maturities. Derivative instruments, consisting entirely of foreign exchange contracts, are stated at their estimated fair values, based on quoted market prices for the same or similar instruments. The counterparties to the agreements relating to the Company's derivative instruments consist of large financial institutions of high credit standing.

The Company's main financial institutions for banking operation held all of the Company's cash and cash equivalents as of March 31, 2016 and March 31, 2015.

The Company's accounts receivable are derived from net revenue to customers and distributors located in the United States and other countries. The Company performs credit evaluations of its customers' financial condition. The Company provides reserves for potential credit losses but has not experienced significant losses to date. There was one customer whose accounts receivable balance represented 10% or more of total accounts receivable, net, as of March 31, 2016 or March 31, 2015. This customer represented 58% and 47% of the accounts receivable balances, as of March 31, 2016 and March 31, 2015, respectively.

The Company currently sells products through its direct sales force and through third-party distributors. There was one direct customer that accounted for 10% or more of total product sales for the fiscal years ended March 31, 2016, 2015 and 2014. This customer represented 57%, 55% and 54% of total product sales for the fiscal years March 31, 2016, 2015 and 2014, respectively.

Inventory

Inventory is stated at the lower of standard cost (which approximates actual cost) or market, with cost determined on the first-in-first-out method. Accordingly, allocation of fixed production overheads to conversion costs is based on normal capacity of production. Abnormal amounts of idle facility expense, freight, handling costs and spoilage are expensed as incurred and not included in overhead. No stock-based compensation cost was included in inventory as of

March 31, 2016 and 2015, respectively.

Property and equipment

Property, equipment and leasehold improvements are stated at cost, net of accumulated depreciation and amortization. Depreciation and amortization are computed on a straight-line basis over the estimated useful lives of the related assets as follows:

Land—not depreciated.

Plant, machinery and equipment—4 to 25 years;

Leasehold improvements—the shorter of the lease term or the estimated useful life of the asset.

Repairs and maintenance expenditures, which are not considered improvements and do not extend the useful life of property and equipment, are expensed as incurred.

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Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by comparing the carrying amount of the assets to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. During the fiscal years ended 2016, 2015 and 2014, no impairment losses have been recorded.

Intangible Assets and Goodwill

Intangible assets related to product licenses are recorded at cost, less accumulated amortization. Intangible assets related to technology and other intangible assets acquired in acquisitions are recorded at fair value at the date of acquisition, less accumulated amortization. Intangible assets are amortized over their estimated useful lives, on a straight-line basis as follows:

Customer relationships—5 years

Brands associated with acquired cell lines—40 years

Product licenses—10 years

Other intangibles assets—7 years

The Company reviews its intangible assets for impairment and conducts the impairment review when events or circumstances indicate the carrying value of a long-lived asset may be impaired by estimating the future undiscounted cash flows to be derived from an asset to assess whether or not a potential impairment exists. If the carrying value exceeds the Company's estimate of future undiscounted cash flows, an impairment value is calculated as the excess of the carrying value of the asset over the Company's estimate of its fair market value. Events or circumstances which could trigger an impairment review include a significant adverse change in the business climate, an adverse action or assessment by a regulator, unanticipated competition, significant changes in the Company's use of acquired assets, the Company's overall business strategy, or significant negative industry or economic trends. No impairment losses have been recorded in any of the years ended March 31, 2016, 2015 or 2014.

Goodwill represents the excess of the purchase price in a business combination over the fair value of tangible and identifiable intangible assets acquired less liabilities assumed. Goodwill resulting from a business combination in 2007 has been fully impaired.

Revenue Recognition

The Company recognizes revenue from product sales when there is persuasive evidence that an arrangement exists, delivery has occurred, the price is fixed or determinable and collectability is reasonably assured. Customers have no right of return except in the case of damaged goods. The Company has not experienced any significant returns of its products. Shipping and handling costs are expensed as incurred and included in cost of product sales. In those cases where the Company bills shipping and handling costs to customers, the amounts billed are classified as revenue.

The Company enters into revenue arrangements that may consist of multiple deliverables of its products and services. The terms of these arrangements may include non-refundable upfront payments, milestone payments, other contingent payments and royalties on any product sales derived on collaboration. Up-front fees received in connection with collaborative agreements are deferred upon receipts, are not considered a separate unit of accounting and are recognized as revenues over the relevant performance periods. Revenues related to research and development services

included in a collaboration agreement are recognized as research and services are performed over the related performance periods for each contract and included in other revenues. A payment that is contingent upon the achievement of a substantive milestone is recognized in its entirety in the period in which the milestone is achieved.

In June 2013, the Company entered into an agreement with Ortho-Clinical Diagnostics Inc. (“Ortho”) to develop a range of rare antisera products. The Company had been working on this project for more than a year before the formal agreement was signed with Ortho. Under the terms of the agreement, the Company is entitled to receive milestone payments of \$2,750 upon the receipt of CE-marks for the rare antisera products, \$1,400 upon the receipt of FDA approval of the rare antisera products and two further milestones of \$500 each upon the updating of the CE-mark and FDA approvals to cover use of the products on Ortho’s automation platform. The Company concluded that as each of these milestones required significant levels of development work to be undertaken and there was no certainty at the start of the project that the development work would be successful, these milestones are substantive and will be accounted for under the milestone method of revenue recognition. During the fiscal year ended March 31, 2014, the Company recognized \$2,750 of milestone revenue relating to the achievement of the CE-mark milestone. The agreement also contains one further milestone of \$650 payable when Ortho orders \$250 of the rare antisera products covered by the agreement. This payment represents a royalty payment and was recognized during the year ended March 31, 2015. During the fiscal year ended March 31, 2016, the Company recognized \$500 of revenue, which related to the achievement of CE-mark approval of the products on Ortho’s automation platform.

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Research and Development

Research and development expenses consist of costs incurred for company-sponsored and collaborative research and development activities. These costs include direct and research-related overhead expenses. Other than materials assessed as having alternative future uses and which are recognized as prepaid expenses, the Company expenses research and development costs, including the expenses for research under collaborative agreements, as such costs are incurred. Where government grants are available for the sponsorship of such research, the grant receipt is included as a credit against the related expense.

Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the fair value of the award and is recognized as an expense on a straight-line basis over the requisite service period, which is generally the vesting period. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's Consolidated Statements of Comprehensive Loss.

In determining fair value of the stock-based compensation payments, the Company uses the Black-Scholes model and a single option award approach for share options and a barrier option pricing model for multi-year performance based restricted share units or MRSUs, both of which require the input of subjective assumptions. These assumptions include: the fair value of the underlying share, estimating the length of time employees will retain their awards before exercising them (expected term), the estimated volatility of the Company's ordinary shares price over the expected term (expected volatility), risk-free interest rate (interest rate), expected dividends and the number of shares subject to awards that will ultimately not complete their vesting requirements (forfeitures).

Share Warrant Liability

The Company has three classes of freestanding warrants to purchase ordinary shares outstanding: (i) warrants issued in December 2013, (ii) pre-funded warrants issued in November 2014 and (iii) warrants issued in August 2015. These warrants do not contain any obligation to transfer value and, as such, the issue of these warrants has been recorded in permanent equity.

The Company also issued warrants to purchase ordinary shares at the time of its initial public offering. These warrants were recorded as a liability because the underlying terms of the warrants contained provisions that may have obligated the Company to transfer value in certain circumstances. The warrants were recorded at fair value upon issuance and were subject to re-measurement to fair value at each balance sheet date, with any change in fair value recognized as component of other income (expense), net on the Consolidated Statements of Comprehensive Loss. These warrants expired on October 26, 2015 and were either exercised prior to that date or expired on that date. As a result, at March 31, 2016 there was no longer any liability related to these warrants.

Derivative Financial Instruments

In the normal course of business, the Company's financial position is routinely subjected to market risk associated with foreign currency exchange rate fluctuations. The Company's policy is to mitigate the effect of these exchange rate fluctuations on certain foreign currency denominated business exposures. The Company has a policy that allows the use of derivative financial instruments to hedge foreign currency exchange rate fluctuations on forecasted revenue denominated in foreign currencies. The Company carries derivative financial instruments (derivatives) on the balance sheet at their fair values. The Company does not use derivatives for trading or speculative purposes. The Company does not believe that it is exposed to more than a nominal amount of credit risk in its foreign currency hedges, as counterparties are large, global and well-capitalized financial institutions. To hedge foreign currency risks, the

Company uses foreign currency exchange forward contracts, where possible and prudent. These forward contracts are valued using standard valuation formulas with assumptions about future foreign currency exchange rates derived from existing exchange rates, interest rates, and other market factors.

The Company considers its most current forecast in determining the level of foreign currency denominated revenue to hedge as cash flow hedges. The Company combines these forecasts with historical trends to establish the portion of its expected volume to be hedged. The revenue and expenses are hedged and designated as cash flow hedges to protect the Company from exposures to fluctuations in foreign currency exchange rates. If the underlying forecasted transaction does not occur, or it becomes probable that it will not occur, the related hedge gains and losses on the cash flow hedge are reclassified from accumulated other comprehensive income (loss) to the consolidated statement of comprehensive loss at that time.

Income Taxes

The Company accounts for income taxes using an asset and liability approach, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements, but

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have not been reflected in taxable income. A valuation allowance is established to reduce deferred tax assets to their estimated realizable value. Therefore, the Company provides a valuation allowance to the extent that is more likely than not that it will generate sufficient taxable income in future periods to realize the benefit of its deferred tax assets.

Pension Obligation

The Company maintains a pension plan covering employees in Switzerland pursuant to the requirements of Swiss pension law. Certain aspects of the plan require that it be accounted for as a defined benefit plan pursuant to Accounting Standards Codification Topic, 715 Compensation – Retirement Benefits or ASC 715. The Company recognizes an asset for the plan’s overfunded status or a liability for the plan’s underfunded status in its Consolidated Balance Sheets. Additionally, the Company measures the plan’s assets and obligations that determine its funded status as of the end of the year and recognizes the change in the funded status within “Accumulated other comprehensive loss”.

The Company uses an actuarial valuation to determine its pension benefit costs and credits. The amounts calculated depend on a variety of key assumptions, including discount rates and expected return on plan assets. Details of the assumptions used to determine the net funded status are set out in Note 11. The Company’s pension plan assets are assigned to their respective levels in the fair value hierarchy in accordance with the valuation principles described in the “Fair Value of Financial Instruments” section above.

Debt Issuance Costs

On September 30, 2015, the Company elected to adopt early the requirements of Accounting Standards Update 2015-03, Interest — Imputation of Interest (Subtopic 835-30) — Simplifying the Presentation of Debt Issuance Costs, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the debt liability rather than as an asset. In view of the refinancing of the Company’s secured credit facility on August 3, 2015 (see note 4), the Company believes that it is preferable to adopt this presentation in the year of refinancing in order to reflect more accurately the assets of the Company and the substance of the financing arrangements. Comparative financial statements of prior years have been adjusted to apply the new presentation retrospectively. This had the effect of reducing “Prepaid expenses and other current assets” and “Other non-current assets” at March 31, 2015 by \$549 and \$366, respectively, with a consequential reduction in “Long term debt, less current portion” of \$915. There has been no impact on the comparative Consolidated Statements of Comprehensive Loss, Statement of Changes in Shareholders’ Deficit or Statements of Cash Flows.

Recent Accounting Pronouncements

The FASB issued ASU 2014-09, Revenue from Contracts with Customers that will supersede virtually all revenue recognition guidance in GAAP. The new standard provides accounting guidance for all revenue arising from contracts with customers and affects all entities that enter into contracts to provide goods or services to their customers (unless the contracts are in the scope of other GAAP requirements). The guidance also provides a model for the measurement and recognition of gains and losses on the sale of certain nonfinancial assets, such as property and equipment, including real estate. The new standard is effective for public entities for fiscal years beginning after 15 December 2017 and for interim periods therein. The Company is in the process of evaluating the impact that adoption of this standard will have on future financial statements.

Note 2. Intangible Assets

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	March 31, 2016			Weighted
	Gross			Ave.
	Carrying Amount	Accumulated Amortization	Net Carrying Amount	Remaining Useful Life
Customer relationships	\$2,829	\$ (2,829)	\$ —	—
Brands associated with acquired				
cell lines	583	(125)	458	31.4 years
Product licenses	748	(304)	444	5.9 years
Other intangibles	184	(184)	—	—
Total	\$4,344	\$ (3,442)	\$ 902	18.9 years

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	March 31, 2015			
	Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Ave. Remaining Useful Life
Customer relationships	\$2,923	\$ (2,923)	\$ —	—
Brands associated with acquired cell lines	603	(115)	488	32.4 years
Product licenses	703	(241)	462	6.6 years
Other intangibles	190	(190)	—	—
Total	\$4,419	\$ (3,469)	\$ 950	19.8 years

Amortization expense was \$89, \$99, and \$103 in financial years 2016, 2015, and 2014, respectively. Total future amortization expense for intangible assets that have definite lives, based upon the Company's existing intangible assets and their current estimated useful lives as of March 31, 2016, is estimated as follows:

2017	\$89
2018	89
2019	89
2020	89
2021	89
Thereafter	457
Total	\$902

Note 3. Debt

Long-term debt comprises:

	March 31, 2016	March 31, 2015
Total debt	\$30,000	\$15,000
Less current portion	(1,000)	(4,500)
Long-term debt	\$29,000	\$10,500
Deferred debt costs, net of amortization	(184)	(428)
Fair value of associated share warrant, net of amortization	(906)	(219)
	\$27,910	\$9,853

The outstanding debt and the fee due on final repayment fall due as follows:

Within 1 year	\$ 1,000
Between 1 and 2 years	12,000
Between 2 and 3 years	12,000
Between 3 and 4 years	5,000
Total debt	\$30,000

On August 3, 2015, the Company drew down \$30 million under a new secured bank facility agreement with MidCap Financial Trust to replace a previous \$15 million facility with MidCap Financial LLC. The new facility is repayable over a four year period with no repayments being due until March, 1, 2017 when the first of 30 equal monthly repayments is due. If the Company achieves CE Mark approvals for the MosaiQ™ instrument and blood grouping consumable, the facility is repayable over a four year period with no repayments until September 1, 2017 when the first of 24 equal monthly repayments is due. The facility bears interest at LIBOR plus 6.7%. The LIBOR rate applicable to the facility is the higher of the actual market rate from time to time or 2.0%. Other expense for the year ended March 31, 2016 included \$0.6 million of previously deferred fees that were expensed as a result of the expansion of the credit facility.

Note 4. Fair Value Measurements

Assets and liabilities measured and recorded at fair value on a recurring basis

The following table summarizes the Company's assets and liabilities that are measured at fair value on a recurring basis, by level, within the fair value hierarchy:

	March 31, 2016			Total
	Level 1	Level 2	Level 3	
Assets:				
Pension plan assets (1)	\$—	\$4,455	\$ —	\$4,455
Total assets measured at fair value	\$—	\$4,455	\$ —	\$4,455

	March 31, 2016			Total
	Level 1	Level 2	Level 3	
Liabilities:				
Foreign currency forward contracts (2)	\$—	\$190	\$ —	\$190
Fair value of share warrants	—	—	—	—
Total liabilities measured at fair value	\$—	\$190	\$ —	\$190

	March 31, 2015			Total
	Level 1	Level 2	Level 3	
Assets:				
Foreign currency forward contracts (2)	\$—	\$—	\$ —	\$—
Total assets measured at fair value	\$—	\$—	\$ —	\$—

	March 31, 2015			Total
	Level 1	Level 2	Level 3	
Liabilities:				
Foreign currency forward contracts (2)	\$199	\$—	\$ —	\$199
Fair value of share warrants	31,011	—	—	31,011
Total liabilities measured at fair value	\$31,210	\$—	\$ —	\$31,210

(1) The fair value of pension plan assets has been determined as the surrender value of the portfolio of active insured employees held within the Swiss Life collective investment fund.

(2) The fair value of foreign currency forward contracts has been determined by calculating the present value of future cash flows, estimated using market-based observable inputs including forward and spot exchange rates and interest rate curves obtained from third party market price quotations.

The change in the estimated fair value of ordinary and preference share warrant liabilities is summarized below:

March 31, 2014	\$421
Transfer of liability to shareholders' equity upon the conversion of the preference	(421)

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share warrant to a warrant in respect of ordinary shares	
Issue of ordinary share warrants as part of the company's initial public offering	8,529
Change in fair value of ordinary share warrants	22,966
Exercise of warrants	(484)
March 31, 2015	\$31,011
Change in fair value of ordinary share warrants	(15,857)
Exercise and expiry of warrants	(15,154)
March 31, 2016	\$—

The carrying amounts of cash and cash equivalents, trade accounts receivable and accounts payable reported in the Consolidated Balance Sheets approximate their respective fair values because of the short term nature of these accounts. The fair value of long-term debt approximates the recorded value.

Note 5. Consolidated Balance Sheet Detail

Inventory

The following table summarizes inventory by category for the periods presented:

	March 31,	March 31,
	2016	2015
Raw materials	\$8,693	\$1,180
Work in progress	2,266	2,071
Finished goods	1,625	1,357
Total inventories	\$12,584	\$4,608

Prepaid expenses and other current assets

At March 31, 2015, prepaid expenses included \$2,655 related to purchases of glass for use at the MosaiQ™ consumable manufacturing facility in Switzerland. At March 31, 2016, the equivalent balance of glass was \$4,008 and is included in inventories.

Property and equipment

The following table summarizes property and equipment by categories for the periods presented:

	March 31,	March 31,
	2016	2015
Land	\$1,480	\$—
Plant and machinery	42,375	21,688
Leasehold improvements	19,440	11,412
Total property and equipment	63,295	33,100
Less: accumulated depreciation	(6,180)	(3,367)
Total property and equipment, net	\$57,115	\$29,733

Plant and machinery at March 31, 2016 and March 31, 2015 included \$26,973 and \$15,721 respectively, of payments on account related to equipment being developed for use at the MosaiQ™ consumable manufacturing facility in Switzerland. This equipment was placed into service in April 2016 and will be depreciated over an eight year life. Depreciation expenses were \$2,856, \$1,185 and \$519 in financial years 2016, 2015, and 2014, respectively. In the financial year ended March 31, 2015, there was a loss on disposal of \$382 related to the retirement of certain items of plant and equipment acquired as part of the lease arrangements for the consumable manufacturing plant in Switzerland.

Accrued compensation and benefits

Accrued compensation and benefits consist of the following:

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	March 31,	March 31,
	2016	2015
Salary and related benefits	\$ 113	\$ 300
Accrued vacation	351	165
Accrued payroll taxes	830	302
Accrued incentive payments	2,000	1,798
Total accrued compensation and benefits	\$3,294	\$2,565

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Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consist of the following:

	March 31,	March 31,
	2016	2015
Accrued legal and professional fees	\$102	\$3,758
Accrued interest	225	112
Goods received not invoiced	911	787
Accrued capital expenditure	2,253	972
Accrued development expenditure	3,533	2,110
Other accrued expenses	2,156	1,048
Total accrued expenses and other current liabilities	\$9,180	\$8,787

Note 6. Commitments and Contingencies

Lease commitments

The Company leases its facilities and certain equipment under operating leases that expire at various dates through 2021. Some of the leases contain renewal options, escalation clauses, rent concessions, and leasehold improvement incentives. Rent expense is recognized on a straight-line basis over the lease term. Rent expense was \$2,923, \$2,111 and \$1,293 in financial years ended March 31, 2016, 2015, and 2014, respectively.

The following is a schedule by years of minimum future rentals on non-cancelable operating leases as of March 31, 2016:

2017	\$2,602
2018	2,082
2019	1,589
2020	1,347
2021	5
Thereafter	—
Total minimum future lease payments	\$7,625

The Company has entered into capital leases for the purchase of equipment that has a gross cost and net book value of \$2,098 and \$1,930, respectively as of March 31, 2016 and \$1,024 and \$737, respectively as of March 31, 2015.

The following is a schedule of future annual repayments on capital leases as of March 31, 2016:

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2017	\$152
2018	1,524
2019	116
2020	74
2021	9
Thereafter	—
Total minimum future lease payments	\$1,875

Purchase obligations

The Company has purchase obligations that are associated with agreements for purchases of goods or services. Management believes that cancellation of these contracts is unlikely and thus the Company expects to make future cash payments according to the contract terms.

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The following is a schedule by years of purchase obligations as of March 31, 2016:

2017	\$35,696
2018	12,385
2019	15,429
2020	28,581
2021	7,348
Thereafter	—
Total minimum future purchase obligations	\$99,438

Government Grant

In 2008, the Company was awarded research and development grant funding from Scottish Enterprise amounting to £1,791 for the development of MosaiQ™. The total grant claimed to March 31, 2016 is £1,790. Regular meetings are held to update Scottish Enterprise with the status of the project and whilst the terms of the grant award provide for full repayment of the grant in certain circumstances, the Company does not consider that any repayment is likely.

Hedging arrangements

The Company's subsidiary in the United Kingdom ("UK") has entered into nine foreign currency forward contracts to sell \$500 and purchase pounds sterling at a rate of £1:\$1.50 in each calendar month through December 2016. The fair values of these contracts, and similar contracts in place at March 31, 2015, amounted to liabilities of \$190 and \$199 at March 31 2016 and March 31, 2015, respectively.

The foreign currency forward contracts were entered into to mitigate the foreign exchange risk arising from the fluctuations in the value of U.S. dollar denominated transactions entered into by our UK subsidiary. These foreign currency forward contracts are designated as cash flow hedges and are carried on the Company's balance sheet at fair value with the effective portion of the contracts' gains or losses included in accumulated other comprehensive income (loss) and subsequently recognized in revenue/expense in the same period the hedged items are recognized.

At inception and at each quarter end, hedges are tested prospectively and retrospectively for effectiveness. Changes in the fair value of foreign currency forward contracts due to changes in time value are excluded from the assessment of effectiveness and are recognized in revenue in the current period. The change in time value related to these contracts was not material for all reported periods. To qualify for hedge accounting, the hedge relationship must meet criteria relating both to the derivative instrument and the hedged item. These criteria include identification of the hedging instrument, the hedged item, the nature of the risk being hedged and how the hedging instrument's effectiveness in offsetting the exposure to changes in the hedged item's cash flows will be measured. There were no gains or losses during the years ended March 31, 2016, March 31, 2015 or March 31, 2014 associated with ineffectiveness or forecasted transactions that failed to occur.

To receive hedge accounting treatment, hedging relationships are formally documented at the inception of the hedge and the hedges must be tested to demonstrate an expectation of providing highly effective offsetting changes to future cash flows on hedged transactions.

Note 7. Geographic Information

The Company operates in one business segment. Revenues are attributed to countries based on the location of the Company's channel partners as well as direct customers.

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The following table represents revenue attributed to countries based on the location of the customer:

	Year ended March 31,		
	2016	2015	2014
Revenue:			
United States	\$8,879	\$8,299	\$9,705
United Kingdom	1,437	938	907
France	3,376	3,419	3,352
Japan	2,836	2,685	2,162
Other foreign countries (1)	1,994	3,067	3,629
	\$18,522	\$18,408	\$19,755

(1) No individual country represented more than 10% of the respective totals.

The table below lists the Company's property and equipment, net of accumulated depreciation, by country. With the exception of property and equipment, the Company does not identify or allocate its assets by geographic area:

	March	March
	31,	31,
	2016	2015
Long-lived assets:		
United Kingdom	\$8,029	\$18,879
Switzerland	49,073	10,854
United States	13	—
	\$57,115	\$29,733

Other income (expense), net includes foreign exchange gains and losses arising on the settlement of transactions in currencies other than the functional currencies of the entity concerned and from retranslation of assets and liabilities denominated in foreign currencies at period end rates. In the years ended March 31, 2016, March 31, 2015 and March 31, 2014 the respective amounts were a gain of \$4,120, a gain of \$1,114 and a loss of \$196.

Note 8. Ordinary and Preference Shares

Ordinary shares

The Company's issued and outstanding ordinary shares consist of the following:

Shares Issued

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	and Outstanding		
	March 31,	March 31,	Par
	2016	2015	value
Ordinary shares	25,408,950	17,020,574	\$ —
Total	25,408,950	17,020,574	\$ —

Preference shares

The Company's issued and outstanding preference shares consist of the following:

	Shares Issued		Liquidation	
	and Outstanding		amount per	
	March	March	March	March
	31,	31,	31,	31,
	2016	2015	2016	2015
7% Cumulative Redeemable Preference shares	666,665	666,665	\$24.34	\$22.76
Total	666,665	666,665		

The 7% Cumulative Redeemable Preference shares were issued to Ortho-Clinical Diagnostics Finco S.Á.R.L., an affiliate of Ortho on January 29, 2015 at a subscription price of \$22.50 per share. These preference shares are redeemable at the request of the shareholder on the "Redemption Trigger Date" which is the date of the fourth anniversary of the date of issue of the preference shares, but the Company may extend the redemption date in one year increments up to the tenth anniversary of the date of issue. Because the 7%

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Cumulative Redeemable Preference shares are redeemable at the option of the shareholders, they are shown as a liability in the Consolidated Balance Sheet.

Note 9. Share-Based Compensation

The Company records share-based compensation expense in respect of options and restricted share units (“RSUs”), including multi-year performance based restricted share units (“MRSUs”) issued under its share incentive plans and in respect of deferred shares issued to employees. Share-based compensation expense amounted to \$2,004 in the year ended March 31, 2016, \$1,138 in the year ended March 31, 2015 and \$933 in the year ended March 31, 2014.

Option Plans

The 2012 Option Plan (the “Option Plan”) was designed in order to grant options on ordinary shares in the capital of the Company to certain of its directors and employees. The purpose of the Option Plan is to provide employees with an opportunity to participate directly in the growth of the value of the Company by receiving options for shares.

Each option converts into one ordinary share of the Company on exercise.

The 2012 Option Plan was approved by the shareholders on February 16, 2012.

The total number of shares in respect of which options may be granted under the 2012 Option Plan is limited at 839,509. Options that lapse or are forfeited are available to be granted again.

Options generally vest over a period of three years but certain employees have shorter vesting periods. The contractual life of all options is 10 years. Options were not exercisable before the Company became a public company and all outstanding options become exercisable in the event of an acquisition of 75% or more of the share capital of the Company by a third party. No further awards will be granted under the 2012 Option Plan.

The 2014 Stock Incentive Plan was approved by the directors and shareholders immediately prior to the Company’s initial public offering in April 2014. The 2014 Plan was designed to provide flexibility to attract and retain the services of qualified employees, officers, directors, consultants and other service providers upon whose judgment, initiative and efforts the successful conduct and development of the business depends, and to provide additional incentives to such persons to devote their effort and skill to the advancement and betterment of the Company, by providing them an opportunity to participate in the ownership of the Company and thereby have an interest in its success and increased value.

Under the 2014 Plan, 1,500,000 ordinary shares were initially reserved for issuance. This number is subject to adjustment in the event of a recapitalization, share split, share consolidation, reclassification, share dividend or other change in the Company’s capital structure and automatically increases annually on April 1 of each year. The plan provides for the issuance of share options, restricted shares, RSUs (including MRSUs) or share appreciation rights (“SARs”). The Company has only issued options, RSUs and MRSUs under the plan prior to March 31, 2016. To the extent that an award terminates, or expires for any reason, then any shares subject to the award may be used again for new grants. However, shares which are (i) not issued or delivered as a result of the net settlement of outstanding SARs or options; (ii) used to pay the exercise price related to outstanding options; (iii) used to pay withholding taxes related to outstanding options or SARs; or (iv) repurchased on the open market with the proceeds from an option exercise,

will not be available for grant under the 2014 Plan.

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Share option activity

The following table summarizes share option activity:

	Number of Share Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Months)
Outstanding — March 31, 2013	369,400	\$ 1.44	116
Granted	477,149	\$ 4.21	120
Exercised	(60,044)	\$ 4.08	—
Forfeited	(7,043)	4.87	—
Outstanding — March 31, 2014	779,462	\$ 2.92	109
Granted	605,250	8.34	120
Exercised	(137,478)	2.23	—
Forfeited	(39,116)	7.93	—
Outstanding — March 31, 2015	1,208,118	\$ 5.58	103
Granted	404,327	14.71	120
Exercised	(8,712)	4.72	—
Forfeited	(13,795)	10.25	—
Outstanding — March 31, 2016	1,589,938	\$ 7.86	96
Exercisable — March 31, 2016	662,261	\$ 4.37	88

The following table summarizes the options granted in the year ended March 31, 2016 with their exercise prices, the fair value of ordinary shares as of the applicable grant date, and the intrinsic value, if any:

Grant Date	Number of Options Granted	Exercise Price	Ordinary Shares	
			Fair Value Per Share at Grant Date	Per Share Intrinsic Value of Options
May 20, 2015	312,300	\$ 15.17	\$ 15.17	\$ 6.08
August 5, 2015	8,000	\$ 16.70	\$ 16.70	\$ 6.54

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September 2, 2015	25,000	\$ 16.34	\$ 16.34	\$ 6.52
October 31, 2015	39,727	\$ 11.62	\$ 11.62	\$ 4.76
November 4, 2015	11,400	\$ 13.00	\$ 13.00	\$ 5.33
February 9, 2016	7,900	\$ 7.34	\$ 7.34	\$ 3.02

Determining the fair value of share options

The fair value of each grant of share options was determined by the Company using the Black-Scholes options pricing model. The total fair value of option awards in the years ended March 31, 2016 and March 31, 2015 amounted to \$2,054 and \$2,108.

Assumptions used in the option pricing models are discussed below. Each of these inputs is subjective and generally requires significant judgment to determine.

Expected volatility. The expected volatility was based on the historical share volatilities of a selection of the Company's publicly listed peers over a period equal to the expected terms of the options as the Company did not have a sufficient trading history to use the volatility of its own ordinary shares.

Fair value of ordinary shares. Since the Company's initial public offering in April 2014, the fair value of ordinary shares has been based on the share price of the Company's shares on the NASDAQ Global Market immediately prior to the grant of the options concerned.

Risk-Free Interest Rate. The risk-free interest rate is based on the UK Government 10 year bond yield curve in effect at the time of grant prior to the initial public offering and 10 year U.S. Treasury Stock for awards from April 2014 onwards.

Expected term. The expected term is determined after giving consideration to the contractual terms of the share-based awards, graded vesting schedules ranging from one to three years and expectations of future employee behavior as influenced by changes to the terms of its share-based awards.

Expected dividend. According to the terms of the awards, the exercise price of the options is adjusted to take into account any dividends paid. As a result dividends are not required as an input to the model, as these reductions in the share price are offset by a corresponding reduction in exercise price.

A summary of the weighted-average assumptions applicable to the share options is as follows:

	Year ended March 31,			
	2016		2015	
Risk-free interest rate	2.26	%	2.64	%
Expected lives (years)	3		3	
Volatility	57.38	%	59.62	%
Dividend yield	—		—	
Grant date fair value (per share)	\$14.71		\$8.34	
Number granted	404,327		605,250	

RSU and MRSU Activity

During the year ended March 31, 2015, the Company awarded 50,000 RSUs to a non-executive director upon his appointment as a director of the Company. These vest in equal annual installments over the four year period following the date of grant. During the year ended March 31, 2016, 12,500 of these RSUs vested resulting in the issuance of 12,500 ordinary shares and at March 31, 2016, 37,500 of these RSUs remained outstanding.

During the year ended March 31, 2016, the Company made various RSU awards. The Company awarded 137,000 MRSUs on May 20, 2015. These MRSUs will vest if the volume weighted average price of the Company's ordinary shares exceeds \$60 for a continuous twenty day period between April 1, 2018 and December 31, 2018. The Company determined the grant date fair value of the MRSUs using a barrier option pricing model with the same grant date fair value per share, risk free interest rate, volatility and dividend yield assumptions as the options awarded on the same date. This resulted in a grant date fair value of \$6.09 per MRSU. On September 2, 2015, the Company issued 25,000 RSUs which will vest if specific sales performance targets are met prior to December 31, 2022. The Company expects these performance targets to be met and share based compensation expense is being recognized on these awards over the period to the date when the sales performance targets are expected to be achieved. The Company also issued 10,000 RSUs on May 20, 2015, 9,867 RSUs on September 4, 2015 and 10,328 RSUs on October 31, 2015 which vest over a two year period from the date of grant. On November 4, 2015, the Company issued 8,000 RSUs which vest over a three year period from the date of grant.

Restricted shares

Share based compensation expense arising on deferred shares amounted to \$156 in the year ended March 31, 2014. As of March 31, 2014, there was no remaining unrecognized compensation cost related to deferred shares.

The fair value of the Company's ordinary shares was \$8.80 per share on March 31, 2016.

As of March 31, 2016, total compensation cost related to share options and RSUs granted but not yet recognized was \$3,900 net of estimated forfeitures. This cost will be amortized to expense over a weighted average remaining period of 1.8 years and will be adjusted for subsequent changes in estimated forfeitures.

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Note 10. Income Taxes

No provision has been made for current or deferred income taxes in any period. The statutory tax rate of the Company in Jersey is 0%. The principal operating subsidiaries operate in the United States, the United Kingdom and Switzerland and are subject to corporate income taxes in those countries. All these entities have incurred trading losses and no corporate income taxes have been provided for. A reconciliation of the income tax expense at the statutory rate to the provision for income taxes is as follows:

	Year ended March 31,		
	2016	2015	2014
Income tax expense at statutory rate	\$—	\$—	\$—
Foreign tax rate differential	1,106	(2,784)	(439)
Increase (decrease) in valuation allowance against deferred tax assets	(1,106)	2,784	439
Provision for income tax	\$—	\$—	\$—

Deferred tax assets and the related valuation allowance were reduced in the fiscal year ended March 31, 2016 despite the reporting of a loss before income tax for the fiscal year. Upon review of the net operating loss carry forwards, it was determined that losses with a tax effected value of \$4,931 were no longer available. The effect of this reduction is included within the foreign tax rate differential.

Significant components of deferred tax assets are as follows:

	March 31, 2016	March 31, 2015
Deferred tax assets:		
Provisions and reserves	\$861	\$270
Net operating loss carry forwards	6,395	8,534
Gross deferred tax assets	\$7,256	\$8,804
Fixed assets basis difference	\$(401)	\$(843)
Gross deferred tax liabilities	\$(401)	\$(843)
Net deferred tax asset	\$6,855	\$7,961
Valuation allowance	(6,855)	(7,961)
Total accrued compensation and benefits	\$—	\$—

The Company maintains a valuation allowance on net operating losses and other deferred tax assets in jurisdictions for which it does not believe it is more-likely-than-not to realize those deferred tax assets based upon all available positive and negative evidence, including historical operating performance, carryback periods, reversal of taxable temporary differences, tax planning strategies, and earnings expectations.

As of March 31, 2016, the Company has net operating loss carry forwards of approximately \$45,347 and \$7,011 of U.S. state net operating losses, which will be available to offset future taxable income. If not used, losses with a tax effect of approximately \$2,838 will expire within five years and losses with a tax effect of \$2,068 will between 2034 and 2036. The remaining portion of the carry forward losses arose in jurisdictions where losses do not expire.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits in tax expense. During the fiscal years ended March 31, 2016, March 31, 2015 and March 31, 2014, the Company had no amounts accrued for interest and penalties. The Company does not currently anticipate that the total amount of unrecognized tax benefits will result in material changes to its financial position within the next 12 months.

The Company has evaluated its tax positions in all jurisdictions at each year end and has concluded that there are no material uncertain tax positions.

The Company files separate company income tax returns in its domestic and foreign jurisdictions. All necessary income tax filings in all jurisdictions have been completed for all years up to and including March 31, 2015 and there are no ongoing tax examinations in any jurisdiction.

No tax charge arose on any element of other comprehensive income.

Note 11. Pension Plans

The Company operates a defined contribution pension scheme. The assets of the scheme are held separately from those of the Company in an independently administered fund. The pension cost charge represents the contribution payable by the Company to the fund during the year. Defined contribution pension costs during the years ended March 31, 2016, 2015 and 2014 amounted to \$580, \$510 and \$349, respectively.

In addition, the Company's Swiss subsidiary has a fully insured pension plan managed by Swiss Life. Under this plan, annual contributions are paid for each employee as determined by Swiss Life and each employee accrues pension benefits with Swiss Life. The risks of disability, death and longevity are also fully insured by Swiss Life. Swiss Life invests the pension contributions and provides a 100% capital and interest guarantee for the pension benefits. These pension arrangements are based on a contract of affiliation between the Company's Swiss subsidiary and the Swiss Life pension foundation, which can be terminated by either party. In the event of a termination, the Company's Swiss subsidiary would have an obligation to find alternative pension arrangements for its employees. Because there is no guarantee that the Swiss employee pension arrangements would be continued under the same conditions, there is a risk, albeit remote, that a pension obligation may fall on the Company's Swiss subsidiary.

These circumstances require that the Swiss employee pension arrangements be treated as a defined benefit plan under Accounting Standards Codification Topic, 715 Compensation – Retirement Benefits or ASC 715-30. Accordingly, an actuarial valuation of the pension obligation has been performed. At March 31, 2016, the accumulated pension obligation amounted to \$8,957 as compared with plan assets of \$4,455. Therefore, the net funded status was an obligation of \$4,502, which has been recorded as a liability on the consolidated balance sheet as of March 31, 2016. The Swiss employee pension arrangements were in place at March 31, 2015, but given the limited number of plan members, the accounting provisions of ASC 715-30 were not applied. The effect on the financial statements of applying the provisions of ASC 715-30 as of March 31, 2015 would have resulted in a net funding obligation of \$1,689 being recorded through other comprehensive income in the year ended March 31, 2015. This amount has been recorded in other comprehensive in the year ended March 31, 2016.

The following provides a reconciliation of the benefit obligations, the plan assets and the funded status.

	Year ended March 31, 2016
Pension benefit obligation, beginning of year	\$—
Service cost	479
Contributions paid by plan participants	2,354
Interest cost	25
Benefits paid	(267)
Plan amendment	(159)
Actuarial loss	6,526
Pension benefit obligation, end of year	\$8,957

	Year ended March 31,
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	2016
Fair value of plan assets, beginning of year	\$—
Adjustment to disclosed value	1,824
Actual return on plan assets	56
Contributions paid by employer	487
Contributions paid by plan participants	2,354
Benefits paid	(267)
Fair value of plan assets, end of year	\$4,455

	Year ended March 31, 2016
Pension benefit obligation, end of year	\$8,957
Fair value of plan assets, end of year	4,455
Net funding obligation, end of year	\$4,502

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The assumptions used to determine the pension obligation are:

	Year ended March 31, 2016
Price inflation	1.00 %
Discount rate	0.45 %
Expected return on plan assets	1.40 %
Average rate of salary increase	1.00 %

Each employee participating in the plan has an individual portfolio that is managed by Swiss Life under a collective arrangement. Plan assets comprise the surrender value of the portfolio of active insured scheme participants. The expected return on plan assets was determined after consideration of current and historical levels of return and discussions with Swiss Life. The discount rate is based on bond yields at March 31, 2016 on the Swiss bond market over a fifteen to twenty year period.

The net pension costs for the year comprises:

	Year ended March 31, 2016
Employer service cost	\$ 479
Interest cost	25
Expected return on plan assets	(25)
Net pension cost for the year	\$ 479

The provision for pension benefit obligation recognized in other comprehensive income comprises:

	Year ended March 31, 2016
Net actuarial loss	\$6,526
Adjustment to disclosed value of plan assets	(1,824)
Plan amendment	(159)
Increase in assets in excess of expected amount	(41)
	\$4,502

The following benefit payments are expected to be paid in the following periods:

2017	\$517
2018	487

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2019	462
2020	441
2021	424
2022 to 2025	1,926

Expected annual employer contributions to the plan in the year ending March 31, 2017 amount to \$664.

Note 12. Net Loss Per Share

In accordance with ASC 260 “Earnings Per Share”, basic earnings available to ordinary shareholders per share is computed based on the weighted average number of ordinary shares outstanding during each period. Diluted earnings available to ordinary shareholders per share is computed based on the weighted average number of ordinary shares outstanding during each period, plus potential ordinary shares considered outstanding during the period, as long as the inclusion of such shares is not anti-dilutive. Potential ordinary shares consist of the incremental ordinary shares issuable upon the exercise of share options (using the treasury shares method), RSUs (including MRSUs) and warrants to acquire ordinary shares and, for the period prior to March 31, 2014, the preference shares in existence at that time which were potentially convertible into ordinary shares.

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The following table sets forth the computation of basic loss per ordinary share. Diluted earnings per share figures are not applicable due to losses:

	Year ended March 31,		
	2016	2015	2014
Numerator:			
Net loss	\$(33,878)	\$(59,059)	\$(10,165)
Net loss available to ordinary shareholders - basic and diluted	\$(33,878)	\$(59,059)	\$(10,165)
Denominator:			
Weighted-average shares outstanding - basic and diluted	19,558,152	14,773,386	186,817
Loss per share - basic and diluted	\$(1.73)	\$(4.00)	\$(54.41)

The following sets out the numbers of the options, RSUs (including MRSUs), warrants to purchase ordinary shares and convertible preference shares excluded from the above computation of earnings per share for the years ended March 31, 2016, March 31, 2015 and March 31, 2014, as their inclusion would have been anti-dilutive.

	March 31,	March 31,	March 31,
	2016	2015	2014
Ordinary shares issuable on exercise of options to purchase			
ordinary shares	1,589,938	1,208,118	779,462
Restricted share units awarded, including the multi-year			
performance related restricted share units	237,695	—	—
Ordinary shares issuable on exercise of warrants at \$16.14 per			
share	111,525	—	—
Ordinary shares issuable on exercise of warrants at \$9.37 per			
share	64,000	64,000	—
Ordinary shares issuable on exercise of warrants at \$8.80 per			
share	—	3,937,894	—
Ordinary shares issuable on exercise of pre-funded warrants at			
\$0.01 per share	850,000	850,000	—
Ordinary shares issuable on conversion of A Preference shares	—	—	4,070,385
Ordinary shares issuable on conversion of B Preference shares	—	—	4,666,690
Ordinary shares issuable on conversion of C Preference shares	—	—	297,333
	2,853,158	6,060,012	9,813,870

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have conducted an evaluation of our disclosure controls and procedures, as that term is defined in Rule 13a-15(e) of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), as of March 31, 2016. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, due to a material weakness in our internal control over financial reporting, which is discussed below in “—Management’s Annual Report on Internal Control over Financial Reporting,” our disclosure controls and procedures were not effective as of March 31, 2016.

(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 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, or COSO.

Based on its evaluation, management identified a material weakness in the operation of our internal controls related to the accounting for pension obligations by our Swiss subsidiary as of March 31, 2016. A material weakness is a control deficiency (within the meaning of Public Company Accounting Oversight Board Auditing Standard No. 2), or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by employees in the normal course of their work.

There was one primary issue related to our Swiss employee pension arrangements that led management to conclude that a material weakness existed. Specifically, we did not record a defined benefit pension plan obligation liability associated with the application of Accounting Standards Codification Topic, 715 Compensation – Retirement Benefits, or ASC-715, in the current year’s comprehensive income when, in fact, a defined benefit pension plan obligation liability should have been recorded.

Management has concluded that we did not design and maintain effective controls to assess the accounting treatment for pension arrangements. Specifically, we did not maintain sufficient expertise and experience in accounting under US GAAP for pension arrangements with a sufficient understanding of local regulations and their US GAAP accounting implications. This material weakness resulted in an accounting error, which was corrected prior to the issuance of the consolidated financial statements for the year ended March 31, 2016.

Because of the material weakness described above, management concluded that, as of March 31, 2016, we did not maintain effective internal control over financial reporting based on the criteria established in Internal Control-Integrated Framework 2013 issued by COSO.

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The Annual Report on Form 10-K does not include an attestation report of our independent registered public accounting firm regarding internal control over financial reporting as a result of an exemption provided to emerging growth companies under the JOBS Act.

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Remediation Plan for Material Weakness in Internal Control over Financial Reporting

We have developed the following plan to remediate the material weakness identified above:

To maintain effective internal controls on an ongoing basis we established in May 2016 a specific internal control procedure related to requirements of ASC-715. In particular, when new entities are set up in countries where the Company lacks the relevant expertise of local regulations, management will obtain appropriate professional advice in the country in order to properly assess and account for any material local arrangements, such as pension schemes, that may require specific consideration under US GAAP.

We anticipate the actions described above and the resulting improvements in controls will strengthen our internal control over financial reporting relating to accounting for pension obligations, addressing the related material weakness that we identified as of March 31, 2016. However, because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all deficiencies have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple errors or mistakes.

(c) Changes in internal control over financial reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of the year ended March 31, 2016 that has materially affected, or is 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 by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 29, 2016.

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 29, 2016.

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

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 29, 2016.

Item 13. Certain Relationships and Related Transactions and Director Independence

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 29, 2016.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 29, 2016.

PART IV

Item 15. Exhibits, Financial Statement Schedules

1. Financial Statements

Our consolidated financial statements, together with the independent registered public accounting firm’s report thereon, are set forth on pages 59 through 83 of this annual report on Form 10-K and are incorporated herein by reference. See Item 8, “Financial Statements and Supplementary Data,” filed herewith, for a list of financial statements.

2. Financial Statement Schedules

All financial statement schedules have been omitted because the required information is not applicable or deemed not material, or the required information is presented in the consolidated financial statements or in the notes to consolidated financial statements filed in response to Item 8 of this annual report on Form 10-K.

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
3.1	Amended Articles of Association (Filed as Exhibit 3.1 of Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)
4.1	Form of Ordinary Shares Certificate (Filed as Exhibit 4.1 of Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)
4.2	Warrant to Purchase C Preference Shares, dated December 6, 2013, issued to Midcap Funding V, LLC (Filed as Exhibit 4.2 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
4.3	Registration Rights Agreement, dated November 25, 2014, by and among Quotient Limited and Visium Balanced Master Fund, Ltd. (Filed as Exhibit 4.1 to our Current Report on Form 8-K on November 26, 2014 and incorporated herein by reference)
4.4	Registration Rights Agreement, dated November 25, 2014, by and among Quotient Limited and the Subscribers named therein (Filed as Exhibit 4.2 to our Current Report on Form 8-K on November 26, 2014 and incorporated herein by reference)
4.5	Form of Pre-Funded Warrant (Filed as Exhibit 4.3 to our Current Report on Form 8-K on November 26, 2014 and incorporated herein by reference)
4.6	Statement of Rights in relation to Preference Shares in the capital of Quotient Limited (Filed as Exhibit 4.1 to our Current Report on Form 8-K on January 29, 2015 and incorporated herein by reference)
4.7	Warrant to Purchase 66,915 Ordinary Shares, dated September 25, 2015, issued to Midcap Financial Trust (filed as Exhibit 4.1 to our Current Report on Form 8-K on October 1, 2015 and incorporated herein by reference)

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- 4.8 Warrant to Purchase 26,023 Ordinary Shares, dated September 25, 2015, issued to Oxford Finance LLC (filed as Exhibit 4.2 to our Current Report on Form 8-K on October 1, 2015 and incorporated herein by reference)
- 4.9 Warrant to Purchase 14,126 Ordinary Shares, dated September 25, 2015, issued to Oxford Finance LLC (filed as Exhibit 4.3 to our Current Report on Form 8-K on October 1, 2015 and incorporated herein by reference)
- 4.10 Warrant to Purchase 4,461 Ordinary Shares, dated September 25, 2015, issued to Flexpoint MCLS SPV LLC (filed as Exhibit 4.4 to our Current Report on Form 8-K on October 1, 2015 and incorporated herein by reference)
- 10.1 Service Agreement, dated February 16, 2012, between Quotient Biodiagnostics Holding Limited (since renamed Quotient Limited) and Paul Cowan (Filed as Exhibit 10.2 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.2 Employment Agreement, dated March 9, 2009, between Alba Bioscience Limited and Jeremy Stackawitz (Filed as Exhibit 10.3 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)

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Exhibit

number Description of exhibit

- 10.3 Service Agreement, dated November 21, 2012, between Quotient Biodiagnostics Holding Limited (since renamed Quotient Limited) and Edward Farrell (Filed as Exhibit 10.4 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.4 Service Agreement, dated August 14, 2012, between Quotient Biodiagnostics Holdings Limited (since renamed Quotient Limited) and Roland Boyd (Filed as Exhibit 10.5 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.5 Employment agreement, dated March 5, 2014, between Quotient Limited and Stephen Unger (Filed as Exhibit 10.6 of Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-194390) on March 26, 2014 and incorporated herein by reference)
- 10.6 Umbrella Supply Agreement, dated December 1, 2004, between Alba Bioscience, a division of the Scottish National Blood Transfusion Service, predecessor to Alba Bioscience Limited, acting on behalf of The Common Services Agency, and Ortho-Clinical Diagnostics Inc. (Filed as Exhibit 10.7 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.7 Assignment Agreement of the Supply Umbrella Agreement, dated September 3, 2007, between Ortho-Clinical Diagnostics Inc. and The Common Services Agency acting through its division the Scottish National Blood Transfusion Service (Filed as Exhibit 10.8 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.8† STRATEC Development Agreement, dated January 7, 2014, between STRATEC Biomedical AG and QBD (QSIP) Limited (Filed as Exhibit 10.9 of Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-194390) on April 3, 2014 and incorporated herein by reference)
- 10.9 Shareholders Agreement, dated February 16, 2012, by and among Quotient Biodiagnostics Holdings Limited (since renamed Quotient Limited), each holder of the Corporation's A Preference Shares, B Preference Shares, Ordinary Shares, A Deferred Shares, B Deferred Shares, C Deferred Shares, A Ordinary Shares and B Ordinary Shares (Filed as Exhibit 10.10 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.10 Future Master Services Agreement, dated April 1, 2013, between Future Diagnostics BV and QDB (QSIP) Limited. (Filed as Exhibit 10.11 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.11 Eysins, Switzerland Lease Agreement, dated March 10, 2010, between Nemaco Fléchères B.V. and Quotient Suisse SA (Filed as Exhibit 10.12 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.12 Eysins, Switzerland, Lease Assignment Agreement, dated December 9, 2013, by and among Fidfund Management SA, Mondelez Europe GmbH, Quotient Suisse SA and Quotient Limited. (Filed as Exhibit 10.13 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)

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- 10.13 Edinburgh, Scotland Lease Agreement, dated July 26, 2007, between the Scottish Ministers and Dalglen (No. 1062) Limited (since renamed Alba Bioscience Limited)(Filed as Exhibit 10.14 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.14 Edinburgh, Scotland, Minute of Variation of Lease and Guarantee, dated September 21, 2011, among Alba Bioscience Limited (formerly Dalglen (No. 1062) Limited, Quotient Biodiagnostics Group Limited, and the Scottish Ministers (Filed as Exhibit 10.15 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.15 Form of Indemnification Agreement (Filed as Exhibit 10.16 of Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)
- 10.16 2012 Option Plan (Filed as Exhibit 10.17 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.17 2014 Stock Incentive Plan (Filed as Exhibit 10.18 of Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)

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Exhibit

number Description of exhibit

- 10.18† TTP Master Development Agreement, dated January 4, 2010, between The Technology Partnership plc and QBD (QS-IP) Limited. (Filed as Exhibit 10.19 of Amendment No. 1 to our Registration Statement on Form S-1 (File No. 333-194390) on March 26, 2014 and incorporated herein by reference)
- 10.19† TTP Intellectual Property Rights Agreement, dated March 4, 2014, between The Technology Partnership plc and QBD (QS-IP) Limited. (Filed as Exhibit 10.20 of Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-194390) on April 3, 2014 and incorporated herein by reference)
- 10.20 First Amendment to the STRATEC Development Agreement, dated March 3, 2014, between STRATEC Biomedical AG and QBD (QS-IP) Limited. (Filed as Exhibit 10.21 of our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)
- 10.21† STRATEC Supply and Manufacturing Agreement, dated April 1, 2014, between STRATEC Biomedical AG and QBD (QS-IP) Limited. (Filed as Exhibit 10.22 of Amendment No. 3 to our Registration Statement on Form S-1 (File No. 333-194390) on April 7, 2014 and incorporated herein by reference)
- 10.22† SCHOTT Supply Agreement, dated March 27, 2014, between Schott Technical Glass Solutions GmbH and QBD (QS-IP) Limited. (Filed as Exhibit 10.23 of Amendment No. 3 to our Registration Statement on Form S-1 (File No. 333-194390) on April 7, 2014 and incorporated herein by reference)
- 10.23 Form of Restricted Stock Unit Award Agreement (Filed as Exhibit 10.24 of Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)
- 10.24 Form of Restricted Stock Award Agreement (Filed as Exhibit 10.25 of Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)
- 10.25 Form of Option Award Agreement (Filed as Exhibit 10.26 of Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)
- 10.26 Form of Letter of Appointment for a Non-Executive Director (Filed as Exhibit 10.27 of Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-194390) on April 15, 2014 and incorporated herein by reference)
- 10.27 Letter dated July 17, 2014 relating to the settlement of a dispute related to an Asset Purchase Agreement dated July 26, 2007 between The Common Services Agency (acting through Scottish National Blood Transfusion Service) and Alba Bioscience Limited (Filed as Exhibit 10.1 to our Quarterly Report on Form 10-K on November 13, 2014 and incorporated herein by reference)
- 10.28 Subscription Agreement, dated November 25, 2014, by and among Quotient Limited and Visium Balanced Master Fund, Ltd. (Filed as Exhibit 10.1 to our Current Report on Form 8-K on November 26, 2014 and incorporated herein by reference)
- 10.29 Subscription Agreement, dated November 25, 2014, by and among Quotient Limited and the Subscribers named therein. (Filed as Exhibit 10.2 to our Current Report on Form 8-K on November 26, 2014 and incorporated herein by reference)

- 10.30 Contract Agreement, dated October 27, 2014, between Quotient Suisse SA and MW High Tech Projects UK Limited t/a SLL. (Filed as Exhibit 10.32 of our Registration Statement on Form S-1 (File No. 333-200938) on December 12, 2014 and incorporated herein by reference)
- 10.31 Subscription Agreement, dated January 29, 2015, between Quotient Limited and Ortho-Clinical Diagnostics Finco S.Á.R.L. (Filed as Exhibit 10.1 of our Current Report on Form 8-K on January 29, 2015 and incorporated herein by reference)
- 10.32† Distribution and Supply Agreement, dated January 29, 2015, between QBD (QS IP) Limited, Quotient Suisse SA and Ortho-Clinical Diagnostics, Inc.
- 10.33 Amended and Restated Credit, Security and Guaranty Agreement, dated as of August 3, 2015, among Quotient Biodiagnostics, Inc., the other Credit Parties party thereto, Midcap Financial Trust and the Lenders from time to time party thereto (filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q on November 4, 2015 and incorporated herein by reference)
- 10.34 Amendment No.1 and Joinder to Credit, Security and Guaranty Agreement, dated as of September 10, 2015, among Quotient Biodiagnostics, Inc., the other Credit Parties party thereto, Midcap Financial Trust and the Lenders from time to time party thereto (filed as Exhibit 10.2 to our Quarterly Report on Form 10-Q on November 4, 2015 and incorporated herein by reference)

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Exhibit

number Description of exhibit

- 10.35 Amendment No.2 to Credit, Security and Guaranty Agreement, dated as of September 25, 2015, among Quotient Biodiagnostics, Inc., the other Credit Parties party thereto, Midcap Financial Trust and the Lenders from time to time party thereto (filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q on November 4, 2015 and incorporated herein by reference)
- 10.36† Second Amendment to STRATEC Development Agreement, dated August 25, 2015, between STRATEC Biomedical AG and Quotient QS IP Ltd. (filed as Exhibit 10.4 to our Quarterly Report on Form 10-Q on November 4, 2015 and incorporated herein by reference)
- 10.37 Construction Contract, dated December 3, 2015, between Quotient Biocampus Limited and MW High Tech Projects UK Limited (filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q on February 10, 2016 and incorporated herein by reference)
- 10.38*† First Amendment to TTP Intellectual Property Rights Agreement, dated March 28, 2016, between The Technology Partnership plc and QBD (QS-IP) Limited
- 12.1* Computation of Ratio of Earnings to Combined Fixed Charges and Preference Share Dividends
- 21.1* List of Subsidiaries.
- 23.1* Consent of Ernst & Young LLP.
- 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.
- 32.1* Certification of the Principal Executive Officer pursuant Section 906 of the Sarbanes-Oxley Act of 2002
- 32.2* Certification of the Principal Financial Officer pursuant Section 906 of the Sarbanes-Oxley Act of 2002
- 101# The following financial statements from the Company's Quarterly Report on Form 10-K for the year ended March 31, 2016, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of March 31, 2016 and 2015, (ii) Consolidated Statements of Comprehensive Loss for the years ended March 31, 2016, 2015 and 2014, (iii) Consolidated Statements of Redeemable Convertible Preference Shares and Changes in Shareholders' Equity for the years ended March 31, 2016, 2015 and 2014, (iv) Consolidated Statements of Cash Flows for the years ended March 31, 2016, 2015 and 2014 and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.

€ Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been submitted separately to the Securities and Exchange Commission.

* Filed herewith.

+ Registrant has omitted portions of the referenced exhibit pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, as amended.

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XBRL information is furnished and not filed for purposes of Section 11 and 12 of the Securities Act of 1933 and Section 18 of the Securities Exchange Act of 1934, and is not subject to liability under those sections, is not part of any registration statement, prospectus or other document to which it relates and is not incorporated or deemed to be incorporated by reference into any registration statement, prospectus or other document.

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Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Edinburgh, Scotland on May 31, 2016

QUOTIENT LIMITED

By: /s/ Paul Cowan
Paul Cowan

Chief Executive Officer and Chairman of the Board
of Directors

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons in the capacities and on the date indicated.

Signature	Title	Date
/s/ Paul Cowan Paul Cowan	Chief Executive Officer and Chairman of the Board of Directors (Principal Executive Officer)	May 31, 2016
/s/ Stephen Unger Stephen Unger	Chief Financial Officer (Principal Financial Officer)	May 31, 2016
/s/ Roland Boyd Roland Boyd	Group Financial Controller and Treasurer (Principal Accounting Officer)	May 31, 2016
/s/ Heino von Prondzynski Heino von Prondzynski	Director	May 31, 2016
/s/ Thomas Bologna Thomas Bologna	Director	May 31, 2016
/s/ Frederick Hallsworth Frederick Hallsworth	Director	May 31, 2016
/s/ Brian McDonough Brian McDonough	Director	May 31, 2016
/s/ Sarah O'Connor Sarah O'Connor	Director	May 31, 2016

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/s/ Zubeen Shroff Zubeen Shroff	Director	May 31, 2016
/s/ John Wilkerson John Wilkerson	Director	May 31, 2016
/s/ Stephen Unger Stephen Unger	Authorized Representative in the United States	May 31, 2016