Quotient Ltd
Form 10-K
June 01, 2015

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended March 31, 2015

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 Bush Loan, Penicuik, Midlothian	Not Applicable

EH26 OPZ, 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
Warrants to purchase Ordinary Shares	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 x

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 x

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 x 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 x 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. x

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

Large accelerated filer ¨ Accelerated filer ¨

Non-accelerated filer x (Do not check if a smaller reporting company) Smaller reporting company ¨

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

As of September 30, 2014, 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 $45.1 million based on the closing sales price of the registrant's ordinary shares on September 30, 2014 as reported on The NASDAQ Global Market.

On May 29, 2015, the registrant had a total of 17,026,690 ordinary shares, nil par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for the 2015 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 Final 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," "c "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 pending or threatened 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 proceeds from exercises of our outstanding warrants, and our estimates regarding our capital requirements and capital expenditures (including the expected cost of a new expanded manufacturing facility in Edinburgh, Scotland); 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 an established, 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 serological 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. Serological disease screening involves the screening of donor blood for unwanted pathogens.

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. MosaiQ™ will initially comprise two separate consumables, one for blood grouping and one for serological disease screening, and a high-throughput instrument. 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.

Our internal feasibility studies have demonstrated a high degree of concordance, across a range of key blood group specificities, between results generated using the MosaiQ™ methodology and results generated using predicate technologies for blood grouping. We used column agglutination technology (or CAT, a blood group testing system that incorporates microcolumns and glass bead microparticles) and, where CAT was not feasible, manual testing techniques as the predicate technologies for our internal feasibility studies. For antigen typing and antibody identification, internal feasibility studies have demonstrated concordance levels exceeding 99% for key blood-group specificities. We expect these results to improve with further optimization of the individual reagent formulations, automation of the manufacturing processes for the MosaiQ™ consumable and greater automation of the testing processes.

In addition, results generated using the MosaiQ ™ methodology demonstrated a high degree of concordance to predicate technologies screening blood for Cytomegalovirus (CMV), Syphilis and Hepatitis B virus (HBV). A feasibility study for CMV and Syphilis was conducted in collaboration with Future Diagnostics and examined a total of 274 positive and negative samples. This feasibility study demonstrated concordance of 99.3% for CMV and 100% for Syphilis. A

feasibility study for HBV was conducted in collaboration with Intuitive Biosciences and examined a total of 96 positive and negative samples. This feasibility study demonstrated sensitivity of 95.8% (23 detected versus 24 positive samples) and 100% specificity (72 negative samples reported as negative). As a result of these positive study results, we are advancing the development of the CMV, Syphilis and HBV assays for inclusion on the MosaiQ™ disease screening consumable. We are also developing additional assays for the detection of Hepatitis C virus (HCV), Human Immunodeficiency virus (HIV), Human T-Lymphotropic virus (HTLV) and Chagas disease. This combination of assays will allow us to offer a full suite of currently mandated serological disease screening tests on a single consumable using MosaiQ™.

We have a proven track record and significant expertise in product development, manufacturing and quality, uniquely tailored to the highly regulated transfusion diagnostics market. 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 testing laboratories. We have also

increased our emphasis on the development, manufacture and sale of 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).

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 are developing additional conventional reagent products for our OEM customers and for sale directly in the United States under the Quotient brand.

On April 30, 2014, we completed our initial public offering of 5,000,000 units at a price of $8.00 per unit, each unit consisting of one ordinary share and one warrant to subscribe for 0.8 of one ordinary share, raising net proceeds of $37.2 million after deducting underwriting discounts and commissions. The other costs of the offering, apart from underwriting discounts and commissions, amounted to $3.6 million. Each warrant permits the holder, prior to October 25, 2015, to subscribe for 0.8 of one new ordinary share at an exercise price equivalent to $8.80 per underlying ordinary share.

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.

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

Conversion of our Eysins, Switzerland manufacturing facility is substantially complete and we have commenced installation of key elements of the initial manufacturing system for MosaiQ™ consumables. We expect to complete formal validation of the initial manufacturing system before the end of 2015.

We expect to begin transferring individual assays for the blood grouping consumable to production in the second quarter of 2015 with completion expected before the end of 2015. We also expect to transfer to production the CMV and Syphilis assays for the initial disease screening consumable in the fourth quarter of 2015, with remaining planned disease screening assays (HBV, HCV, HIV, HTLV and Chagas) for the full disease screening consumable expected to be transferred to production in the first half of 2016.

The MosaiQ™ instrument is being developed by STRATEC Biomedical AG, or STRATEC, our instrument-manufacturing partner. We expect to start taking delivery of MosaiQ™ instruments for use in final assay validation and field trials in the fourth quarter of 2015.

We plan to commence formal field trials in the first half of 2016 and file necessary regulatory submissions in the second half of 2016, first in Europe and then in the United States, to obtain required marketing clearances. If licensed for sale, we anticipate commercial launch for both the MosaiQ™ blood grouping consumable and the initial MosaiQ™ disease screening consumable in Europe during the second half of 2016 and in the United States during the second half of 2017. We anticipate commercial launch of the full MosaiQ™ disease screening consumable in Europe during the second half of 2017 and in the United States during 2018.

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 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 and increasing 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.

We believe both donor collection agencies and hospitals would prefer to fully characterize donor units 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 nucleic acid). 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 disease screening is already largely automated. However, it is typically undertaken using two separate instrument platforms, neither of which is 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 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 add 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. However, neither of the two most widely used serological disease screening platforms, Abbott's Prism and Ortho's Summit, are integrated with existing blood grouping instrument platforms that are utilized within the donor testing environment. 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.

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
Serologically screen donor blood for specific viruses.

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 all 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. In a donor testing environment both consumables have been designed to run simultaneously, utilizing the same donor sample and the same MosaiQ™ instrument. In a patient testing environment, we would expect that only the blood grouping consumable would be utilized.

The MosaiQ™ blood grouping consumable will consist of two protein microarrays: one printed with red blood cells and the other printed with antibodies. Our novel approach incorporates existing, well-characterized tests for blood group antigens and antibodies on a single consumable for the global market. Each consumable will consist of two microarrays – one for antigen typing and one for antibody identification. 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 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.

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 900 to 1,000 consumables per eight-hour shift, giving a capacity to test 450 to 500 donor samples (utilizing a blood grouping consumable and a disease screening consumable) or 900 to 1,000 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 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 disease screen in a donor testing environment, with the results being reported through existing laboratory information management systems (or LIMS).

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. Advanced prototype units of the high-throughput instrument have been delivered to us and units for use in final assay validation and field trials are expected to be delivered to us in the fourth quarter of 2015.

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.

MosaiQ™ Development and Commercial Scale-Up

MosaiQ™ is at an advanced stage of development and we are at an advanced stage of industrial scale-up for final product validation and commercialization.

We have conducted extensive feasibility work internally to demonstrate the performance of the MosaiQ™ methodology compared with predicate blood grouping technologies. Development and manufacturing pathways to adapt each of the assays for inclusion on the MosaiQ™ blood grouping consumable are well defined. For the disease screening consumable, we are following the same development pathway for each of the assays to be included. We are optimizing individual assays to be included on the MosaiQ™ consumables in parallel with the building of the initial MosaiQ™ consumable manufacturing system and the development of the MosaiQ™ instrument.

Conversion of our Eysins, Switzerland manufacturing facility is substantially complete and we have commenced installation of key elements of the initial manufacturing system for MosaiQ™ consumables. We expect to complete formal validation of the initial manufacturing system before the end of 2015.

We expect to begin transferring individual assays for the blood grouping consumable to production in the second quarter of 2015 with completion expected before the end of 2015. We also expect to transfer to production the CMV and Syphilis assays for the initial disease screening consumable in the fourth quarter of 2015, with remaining planned disease screening assays (HBV, HCV, HIV, HTLV and Chagas) for the full disease screening consumable expected to be transferred to production in the first half of 2016.

Development of the MosaiQ™ instrument is also at an advanced stage. We have received advanced prototype instruments from STRATEC for evaluation, which have met certain agreed-upon functional requirements. We expect to use these prototype instruments to undertake a large-scale validation study in the middle of 2015, prior to taking delivery of MosaiQ™ instruments in the fourth quarter of 2015 for use in final assay validation and field trials.

We plan to commence formal field trials in the first half of 2016 and file necessary regulatory submissions in the second half of 2016, first in Europe and then in the United States, to obtain required marketing clearances. 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 disease screening consumable, comprising tests for CMV and Syphilis, will be subject to a 510(k) filing, while the more comprehensive disease screening consumable, comprising all mandated serological tests, will be subject to BLA approval. The instrument is expected to be classified as a Class II medical device.

If licensed for sale, we anticipate commercial launch for both the MosaiQ™ blood grouping consumable and the initial MosaiQ™ disease screening consumable in Europe during the second half of 2016 and in the United States during the second half of 2017. We anticipate commercial launch of the full MosaiQ™ disease screening consumable in Europe during the second half of 2017 and in the United States during 2018.

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 39 conventional reagent products focused on blood grouping and we have over 15 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 950 hospitals, donor collection agencies and independent testing laboratory customers throughout the United States. Global direct sales, including sales to distributors, accounted for 30% of our product sales in the year ended March 31, 2015 and 31% in the year ended March 31, 2014.

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 70% of product sales in the year ended March 31, 2015 and 69% in the year ended March 31, 2014. 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 55% and 54% of our product sales in the years ended March 31, 2015 and 2014, 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 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 expect to install the final elements of the initial manufacturing system at the facility during the second and third quarters of 2015. Formal validation of the initial manufacturing system at the Eysins facility is expected to be completed before the end of 2015.

The Technology Partnership plc

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 $14.1 million using exchange rates on March 31, 2015, payable upon completion of pre-

agreed project development milestones. 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 $55.6 million using exchange rates on March 31, 2015. 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 $10.1 million using exchange rates on March 31, 2015. 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 $7.8 million using exchange rates on March 31, 2015.

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, 2015, we had nine 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 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, 2015, we had 82 employees engaged in research and development functions. In addition, over 50 engineers and scientific staff employed by TTP and STRATEC have been assigned to various MosaiQ™ development activities.

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 Bio-Rad. 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 and Bio-Rad are the principal instrument providers for serological disease screening.

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 Diagast 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 Biomedi 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 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, 2015 and positions, and a brief account of the business experience of the individuals who serve as our executive officers.

Name	Age	Position
Paul Cowan	54	Chairman & Chief Executive Officer
Jeremy Stackawitz	40	President
Edward Farrell	45	President
Stephen Unger	45	Chief Financial Officer
Roland Boyd	58	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 Immunohematology 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 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, 2015, we had 232 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, Newton, 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, 2015, we had an accumulated deficit of $74.4 million. We expect our operating losses to continue at least for the next two years 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 remaining development costs for MosaiQ™ from a combination of funding sources, including through the use of existing cash balances, extension or expansion of our credit facilities or the issuance of new equity. Our operating plans for the financial year ending March 31, 2016 reflect an expectation that substantially all of our outstanding warrants from our initial public offering, which expire on October 25, 2015, will be exercised before that date. If significant exercises of these warrants do not occur, we may need or decide to raise additional funds through public or private debt or equity financing or through other means. We cannot be certain that we will be able to obtain this or other 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 warrants or options 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.

We have experienced significant revenue growth in a short period of time. 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;
- 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 disease screening consumable, comprising two tests, CMV, and syphilis. The final 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.

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

While we have developed working prototypes of the 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 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 building, installation and 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 64% of our total revenues and product sales to Ortho accounted for 55% of our total revenues in the year ended March 31, 2015. 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.

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.

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 time to design and build 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 plan to build 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 plan to build 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.

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 $15 million term loan agreement with MidCap Financial 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 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, 2015 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 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;
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™.

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:

fines 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, such as the warning letter we received from the FDA in 2009 regarding compliance with current good manufacturing practices at our Edinburgh facility regarding various antisera products. Following corrective actions that took place between February and April 2009, we received a response acceptance letter from the FDA in June 2009. We have not received any such warning letters or untitled letters since this time.

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.

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. For example, it will be necessary for us to re-file a BLA that we submitted in 2013 for the sale of additional monoclonal antibody products as a result of application deficiencies brought to our attention by the FDA. Our BLA application was not accepted by the FDA as a result of industry-wide changes in study design requirements, while previously-accepted product manufacturing and stability documentation was also rejected. We established a dedicated team to address the deficiencies and have discussed the team’s mandate with the FDA. These efforts were completed in April 2014 and the findings will be incorporated into subsequent FDA submissions and facility audits. We have also de-emphasized the products represented by this BLA in our conventional reagent development plan, preferring to focus on higher value programs with shorter development timelines. 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 wilfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

The federal Physician Payment Sunshine Act requirements under the PPACA (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 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 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 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.

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 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 Securities

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 securities 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. In addition, as an emerging growth company, we are not required to provide five years of selected financial data in this Annual Report. 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 securities less attractive because we may rely on these exemptions. If some investors find our securities less attractive as a result, there may be a less active trading market for our securities and the price of our securities 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 securities is likely to be volatile, and purchasers of our securities could incur substantial losses.

Like other early-stage medical diagnostic companies, the market price of our securities is likely to be volatile. The factors below may also have a material adverse effect on the market price of our securities:

fluctuations in our results of operations;
our ability to enter new markets;
negative publicity;
changes in securities or industry analyst recommendations regarding our company, the sectors in which we operate, the securities market generally, conditions in the financial markets and the perception of our ability to raise additional funding;
regulatory developments affecting MosaiQ™ or our industry, including announcement of new adverse regulatory decisions in respect of MosaiQ;™
announcements of studies and reports relating to our products, including MosaiQ,™ 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;
release or expiry of lock-up or other transfer restrictions on our outstanding securities subject to such restrictions; and
sales or perceived sales of additional ordinary shares or warrants.

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 or warrants 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 or warrants to decline. We had outstanding 17,020,574 ordinary shares as of March 31, 2015, of which approximately 5,207,705 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, 2015, 4,851,894 ordinary shares were subject to outstanding warrants at a weighted average exercise price of $7.27 per share and 1,208,118 ordinary shares were subject to outstanding options at a weighted exercise price of $5.58 per share. To the extent any of these shares are sold into the market, particularly in substantial quantities, the market price of our securities 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 the term loan agreement with MidCap Financial, we are precluded from paying any cash dividends without MidCap Financial'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 securities.

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

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

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

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

Our ordinary shares and warrants 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 or warrants being removed from listing on NASDAQ. If any of our ordinary shares or warrants were to be delisted, the liquidity of our ordinary shares or warrants could be adversely affected and the market price of our ordinary shares or warrants could decrease. Delisting could also adversely affect the ability of a holder of our securities to trade or obtain quotations on our securities 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 securities. You may also not be able to resell your ordinary shares or warrants at or above the price you paid for such securities or at all.

Holders of our warrants will have no rights as ordinary shareholders until such holders exercise their warrants and acquire our ordinary shares.

Until holders of warrants acquire our ordinary shares upon exercise of the warrants, holders of warrants will have no rights with respect to the ordinary shares underlying such warrants. Upon exercise of the warrants, the holders thereof will be entitled to exercise the rights of an ordinary shareholder only as to matters for which the record date occurs after the exercise date.

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 4,922,368 outstanding warrants to purchase 3,937,894 ordinary shares at an exercise price of $8.80 per whole ordinary share (subject to adjustment in certain circumstances). 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. The anti-dilution protections in the warrants sold in our initial public offering, which include full ratchet anti-dilution protection in the event of certain equity issuances below the then existing exercise

price of the warrants, could further dilute the ownership of existing shareholders. Further, if these warrants are exercised at any time in the future at a price lower than the book value per share of our ordinary shares, existing shareholders could suffer dilution of their investment.

The warrants sold in our initial public offering may not have any value.

The warrants sold in our initial public offering will expire at 5:30 p.m. EST on October 25, 2015 unless we in our sole discretion extend the expiration date. In the event our ordinary share price does not exceed the exercise price of the warrants during the period when the warrants are exercisable, the warrants may not have any value.

An effective registration statement may not be in place when an investor desires to exercise warrants, thus precluding such investor from being able to exercise his, her, or its warrants and causing such warrants to be practically worthless.

No warrant sold in our initial public offering will be exercisable and we will not be obligated to issue ordinary shares unless at the time such holder seeks to exercise such warrant, a registration statement relating to the ordinary shares issuable upon exercise of the warrant is effective and current. Under the terms of the warrants, we have agreed to use our best efforts to meet these conditions and to maintain an effective registration statement and a current prospectus relating to the ordinary shares issuable upon exercise of the warrants until the termination date of the warrants. However, we cannot assure you that we will be able to do so, and if we do not maintain an effective registration statement or current prospectus related to the ordinary shares issuable upon exercise of the warrants, holders will be unable to exercise their warrants and we will not be required to net cash settle or cash settle any such warrant exercise. If a registration statement is not effective or the prospectus relating to the ordinary shares issuable upon the exercise of the warrants is not current, the warrants held by investors may have no value, the market for such warrants may be limited, and such warrants may expire worthless.

An investor will only be able to exercise a warrant if the issuance of ordinary shares upon such exercise has been registered or qualified or is deemed exempt under the securities laws of the state or other jurisdiction of residence of the holder of the warrants.

No warrants sold in our initial public offering will be exercisable and we will not be obligated to issue ordinary shares unless the shares issuable upon such exercise have been registered or qualified or deemed to be exempt under the securities laws of the state or other jurisdiction of residence of the holder of the warrants. Our ordinary shares are listed on NASDAQ, which provides an exemption from registration in every U.S. state. Accordingly, we believe holders in every state will be able to exercise their warrants as long as our registration statement is effective and our prospectus relating to the ordinary shares issuable upon exercise of the warrants is current. However, we cannot assure you of this fact. As a result, the warrants may be deprived of any value, the market for the warrants may be limited, and the holders of warrants may not be able to exercise their warrants if the ordinary shares issuable upon such exercise are not registered or qualified or exempt from registration or qualification in the jurisdictions in which the holders of the warrants reside.

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

Our ordinary shares and warrants 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 initial public offering 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 or warrants.

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 or warrants, 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 are a PFIC for our taxable year ended March 31, 2015 and do not expect to be a PFIC for the taxable year ending March 31, 2016 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 or warrants 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, 2017. 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. security holders 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.

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 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, 2015
U.S. Direct Sales Operation	Chapel Hill, N.C., USA	1,000	—	Renewed monthly

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. We plan to replace and expand our existing Edinburgh manufacturing facility with a new facility in Edinburgh for the development and manufacture of conventional reagent products.

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.

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. Prior to our initial public offering, there was no public market for our securities. On May 29, 2015, the last reported sale price of our ordinary shares on NASDAQ was $15.40 per share and the last reported price of our warrants on NASDAQ was $5.60 per warrant.

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:

Fiscal Year Ended March 31, 2015	High	Low
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 29, 2015, there were 27 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 May 27, 2014, the date on which our ordinary shares commenced trading on NASDAQ, through March 31, 2015 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 May 27, 2014.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents certain information about our equity compensation plans as of March 31, 2015:

Name of Plan	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]	1,258,118	$5.36	888,913
Equity compensation plans not approved by shareholders	—	—	—

(1) Composed of the 2013 Enterprise Management Plan, pursuant to which 634,568 ordinary shares are issuable upon exercise of outstanding options and rights at a weighted average exercise price of $3.07, and the 2014 Stock Incentive Plan, pursuant to which 623,550 ordinary shares are issuable upon exercise of outstanding options and rights at a weighted average exercise price of $7.68. 12,463 ordinary shares remain available for future issuance under the 2013 Enterprise Management Plan and 876,450 ordinary shares remain available for future issuance under the 2014 Stock Incentive Plan.

Use of Proceeds from Initial Public Offering

On April 24, 2014, the SEC declared effective our registration statement on Form S-1 (File No. 333-194390) in connection with our initial public offering. As of March 31, 2015, we estimate that we have used all of the net proceeds from our initial public offering as follows: approximately $24 million of the net proceeds on the conversion of the MosaiQ™ manufacturing facility and the design and building of the initial manufacturing system for MosaiQ™ consumables and approximately $9 million on development of the initial MosaiQ™ consumables and instrument platform.

Recent Sale of Unregistered Securities

Since April 1, 2014, we issued the following securities that were not registered under the Securities Act.

On April 3, 2014, we issued 29,114,088 ordinary shares in connection with the conversion of our then outstanding preference shares, A ordinary shares and B ordinary shares immediately prior to our initial public offering. All our outstanding ordinary shares were then subsequently consolidated at a ratio of 32 new ordinary shares to every 100 issued ordinary shares. In addition, certain shares held by certain existing shareholders were further consolidated or were sub-divided.

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. This private placement was completed on November 28, 2014. Fees totaling approximately $2.0 million were paid to the placement agent, Jefferies LLC, for its services in connection with this private placement.

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. This transaction was completed on January 30, 2015.

The above issuances were exempt from registration under the Securities Act under Section 3(a)(9) thereof, as transactions involving exchanges with existing security holders, or under Section 4(a)(2) thereof and Rule 506 of Regulation D promulgated thereunder, 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 (other than the transactions involving conversions of previously issued securities) 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, 2015, 2014 and 2013 and the consolidated balance sheet data as of March 31, 2015 and 2014 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 years ended March 31, 2012 and 2011 and the consolidated balance sheet data as of March 31, 2013 and 2012 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,				
	2015	2014	2013	2012	2011
	(in thousands, except share and per share data)				
Consolidated statement of loss:					
Revenue:					
Product sales	$17,658	$16,987	$13,753	$11,550	$9,545
Other revenues	750	2,768	618	669	489
Total revenue	18,408	19,755	14,371	12,219	10,034
Cost of revenue	(9,763)	(8,406)	(7,169)	(6,749)	(5,628)
Gross profit	8,645	11,349	7,202	5,470	4,406
Operating expenses:					
Sales and marketing	(2,750)	(2,705)	(2,252)	(1,674)	(1,456)
Research and development, net of government grants	(19,216)	(8,066)	(2,617)	(1,749)	(1,703)
General and administrative expense:					
Compensation expense in respect of share options and management equity incentives	(1,138)	(933)	(471)	—	—
Other general and administrative expenses	(15,255)	(8,537)	(6,353)	(6,011)	(5,346)
Total general and administrative expense	(16,393)	(9,470)	(6,824)	(6,011)	(5,346)
Total operating expense	(38,359)	(20,241)	(11,693)	(9,434)	(8,505)
Operating loss	(29,714)	(8,892)	(4,491)	(3,964)	(4,099)
Other expense:					
Interest expense, net	(2,315)				