

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

**FORM 10-K**

(Mark One)

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

For the fiscal year ended March 31, 2019

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)  
**B1, Business Park Terre Bonne,**  
**Route de Crassier 13,**  
**1262 Eysins, Switzerland**  
(Address of Principal Executive Offices)

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

Not Applicable  
(Zip Code)

011-41-22-716-9800

(Registrant's Telephone Number, Including Area Code)

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

Title of each class  
Ordinary Shares, nil par value

Trading Symbol  
QNT

Name of exchange on which registered  
The Nasdaq Global Market

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

None

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

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

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

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

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>		
Smaller reporting company	<input checked="" type="checkbox"/>	Emerging growth company	<input checked="" type="checkbox"/>

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

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

As of September 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the registrant's ordinary shares held by non-affiliates was approximately \$180.5 million based on the closing sales price of the registrant's ordinary shares on September 30, 2018 as reported on The Nasdaq Global Market.

On May 28, 2019, the registrant had a total of 66,179,110 ordinary shares, nil par value, outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the registrant's definitive proxy statement for the 2019 annual meeting of shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

## TABLE OF CONTENTS

	Page
<u>PART I</u>	
<u>Item 1. Business</u>	2
<u>Item 1A. Risk Factors</u>	15
<u>Item 1B. Unresolved Staff Comments</u>	39
<u>Item 2. Properties</u>	39
<u>Item 3. Legal Proceedings</u>	39
<u>Item 4. Mine Safety Disclosures</u>	39
<u>PART II</u>	
<u>Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	40
<u>Item 6. Selected Consolidated Financial Data</u>	43
<u>Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operation</u>	44
<u>Item 7A. Quantitative and Qualitative Disclosures About Market Risk</u>	61
<u>Item 8. Financial Statements and Supplementary Data</u>	62
<u>Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure</u>	90
<u>Item 9A. Controls and procedures</u>	90
<u>Item 9B. Other information</u>	91
<u>PART III</u>	
<u>Item 10. Directors, Executive Officers and Corporate Governance</u>	92
<u>Item 11. Executive Compensation</u>	92
<u>Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters</u>	92
<u>Item 13. Certain Relationships and Related Transactions and Director Independence</u>	92
<u>Item 14. Principal Accounting Fees and Services</u>	92
<u>PART IV</u>	
<u>Item 15. Exhibits, Financial Statement Schedules</u>	93
<u>Item 16. Form 10-K Summary</u>	97
<u>Signatures</u>	98

---

## 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 I, Item 1: “Business,” Part I, Item 1A: “Risk Factors,” and Part II, Item 7: “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” but are also contained elsewhere in this Annual Report. 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,” “continue,” “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 continuing development, regulatory approval and commercialization of MosaiQ™ by us;
- the design of blood grouping and disease screening capabilities of MosaiQ, the potential for the expansion of our MosaiQ technology into the larger clinical diagnostics market 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 products;
- future demand for our conventional reagent products and our ability to meet such demand;
- our ability to manage the risks associated with international operations;
- anticipated changes, trends and challenges in our business and the transfusion diagnostics market;
- the effects of competition;
- the expected outcome or impact of litigation;
- our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- our ability to extend the lease of our manufacturing facility located in Eysins, Switzerland;
- our anticipated cash needs, including the adequacy of our available cash and short-term investment balances relative to our forecasted cash requirements for the next twelve months, our expected sources of funding, and our estimates regarding our capital requirements and capital expenditures; and
- our plans for executive and director compensation for the future.

You should refer to Part I, Item 1A: “Risk Factors” in this Annual Report for a discussion of other important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Annual Report will prove to be accurate. Further, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us that we will achieve our objectives and plans in any specified time frame, or at all. The forward-looking statements in this Annual Report represent our views only as of the date of this Annual Report. Subsequent events and developments may cause our views to change. While we may elect to update these forward-looking statements at some point in the future, we undertake no obligation to publicly update any forward-looking statements, except as required by law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this Annual Report.

## PART I

### Item 1. Business

#### Overview

We are a commercial-stage diagnostics company committed to reducing healthcare costs and improving patient care through the provision of innovative tests within established markets. Our initial focus is on blood grouping and donor disease screening, which is commonly referred to as transfusion diagnostics. Blood grouping involves specific procedures performed at donor or patient testing laboratories to characterize blood, which includes antigen typing and antibody detection. Disease screening involves the screening of donor blood for unwanted pathogens using two different methods, a serological approach (testing for specific antigens or antibodies) and a molecular approach (testing for DNA or RNA). We believe that the MosaiQ platform may also have application beyond transfusion diagnostics in the larger clinical diagnostics market where testing currently performed using separate immunoassay and molecular testing techniques for a single diagnosis could be combined on one testing technology permitting multiple tests simultaneously with a simplified workflow.

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 microarrays, one for immunohematology (blood grouping), or IH, and one for serological disease screening, or SDS, and a high-throughput instrument. We are also developing a third microarray for molecular disease screening. We believe MosaiQ has the potential to transform transfusion diagnostics, significantly reducing the cost of blood grouping in the donor and patient testing environments, 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 is expected to be significantly quicker than existing methods for extended antigen typing and antibody detection 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. Cost savings and efficiencies should also be available to customers that adopt MosaiQ, as a result of:

- consolidation of multiple instrument platforms in donor testing laboratories;
- automation, which will help to address shortages of skilled technicians;
- better workflow, which will lead to a better cost position, addressing budget constraints;
- comprehensive characterization of donor or patient blood, eliminating the need for routine manual testing typically undertaken by skilled technicians; and
- higher throughput and productivity per square meter.

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

Our initial aim is to provide donor testing laboratories with a single instrument platform to be utilized for blood grouping and, if applicable, both serological and molecular disease screening for donated red blood cells and plasma. Based on historical annual blood donations collected by our key target donor testing customers, we estimate that the potential market for MosaiQ microarrays (for blood grouping, serological disease screening and molecular disease screening) should exceed 100 million microarrays per annum following receipt of applicable regulatory clearances and approvals for MosaiQ.

We also believe that MosaiQ may have the potential for use beyond transfusion diagnostics in the larger clinical diagnostics market, and are evaluating the potential for our technology as a platform for diagnosis and monitoring of other disease states. We have identified opportunities for future partnership and development in relation to disease states for which a broad array of tests are required using multiple testing modalities for a single diagnosis or for ongoing therapy monitoring.

We have a proven track record and significant expertise in product development, manufacturing and quality assurance, tailored to the highly regulated transfusion diagnostics market. We currently derive revenue from a portfolio of products used for blood grouping, as well as whole blood controls used daily for quality assurance testing of third-party blood grouping instruments. We have introduced a range of FDA-licensed products in the United States under the Quotient brand, which we sell directly to donor testing laboratories, hospitals and independent patient testing laboratories. We also develop, manufacture and sell conventional reagent products to original equipment manufacturers, or OEMs, such as Ortho-Clinical Diagnostics, Inc. (or Ortho), Bio-Rad Laboratories, Inc. (or Bio-Rad) and Grifols S.A. (or Grifols). In March and June 2017 the FDA licensed a range of conventional reagent products developed and manufactured by us for use on instrument and semi manual testing platforms commercialized by Ortho.

From our incorporation in 2012 to March 31, 2019, we have raised \$160.0 million of gross proceeds through the private placement of our ordinary and preference shares and warrants, \$250.1 million of gross proceeds from public offerings of our shares and issuances of ordinary shares upon exercise of warrants and \$120.0 million of gross proceeds from the issuance of 12% Senior Secured Notes due 2024 (which we refer to as the Secured Notes). In addition, on March 23, 2018, we raised \$20.9 million from the sale and leaseback of our recently completed conventional reagents manufacturing facility near Edinburgh, Scotland, which we refer to as the Allan Robb Campus, or ARC, facility.

On April 30, 2019, we were notified that our initial MosaiQ IH microarray received CE Marking approval in Europe. This notification satisfied a condition under the purchase agreements we entered into in January 2019 for the sale of an additional \$25 million of Secured Notes. On May 15, 2019, we issued these additional Secured Notes for gross proceeds of \$25 million.

#### **Our Market Opportunity**

The global transfusion diagnostics market is large and well established. Total annual product sales in this market amounted to \$3.3 billion in 2016, of which the United States accounted for \$0.9 billion of sales. Product sales comprise the sale of kits and reagents and instruments. In 2016, we believe blood grouping accounted for \$1.0 billion of product sales, disease screening using serological methods accounted for \$0.7 billion of sales and disease screening using molecular methods accounted for \$1.6 billion of sales. We believe product sales in 2016 to the highly concentrated donor testing market, which includes diagnostic laboratories, accounted for approximately \$1.8 billion of sales, while patient testing and others accounted for the remaining \$1.5 billion of sales. Performed primarily within hospitals, the patient testing market is highly fragmented.

According to the World Health Organization, 56 million blood donations were collected globally in 2013 within “high-income” countries located in North America, Western Europe and Eastern Asia. In the United States, between 16 and 17 million units of whole blood and red blood cells were donated during 2014, based on data from the American Association of Blood Bankers and the American Red Cross. 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 \$219. 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 are 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.

Beyond transfusion diagnostics we plan to pursue the development of immunoassay and molecular testing opportunities for the MosaiQ platform technology within the broader clinical diagnostics market place, forecasted to reach \$40 billion annually by 2023.

## Our Strategy

Our strategy is based on the development and commercialization of a flexible and unique microarray technology and manufacturing capability for serological and molecular testing across a broad array of medical and life science applications. Our initial strategic focus is on the development and commercialization of a range of consumables (or microarrays) to address the global transfusion diagnostics market. Each microarray will incorporate existing, well characterized assays to undertake:

- (i) a comprehensive characterization of donor and patient blood, including extended antigen typing and antibody detection/identification. Ultimately, we expect there to be two blood grouping microarrays, one for the donor testing market and one for the patient testing market. We refer to the blood grouping microarrays as the MosaiQ IH Microarray;
- (ii) all mandated serological disease screening tests for donor red blood cells or source plasma. We refer to the serological disease screening microarrays as the MosaiQ SDS Microarray. The initial MosaiQ SDS Microarray will comprise assays to detect CMV and Syphilis. We expect to follow our initial MosaiQ SDS Microarray launch with the launch of a range of additional expanded MosaiQ SDS Microarrays incorporating all remaining mandated serological disease screening assays, depending upon the final application for the product; and
- (iii) all mandated molecular disease screening tests for donor red cells or source plasma. We refer to the molecular disease screening microarray as the MosaiQ MDS Microarray.

Together, we refer to the MosaiQ IH Microarray, MosaiQ SDS Microarray and MosaiQ MDS Microarray as MosaiQ Microarrays.

We manufacture the MosaiQ Microarrays at our state-of-the-art manufacturing facility located in Eysins, Switzerland, which received its ISO 13485: 2016 certification in December 2018.

Development of the MosaiQ Instrument and formal validation was completed during 2018 and we took delivery of the first commercially ready MosaiQ Instrument in 2018. The MosaiQ Instrument was self certified and received CE Marking approval in Europe during 2018.

Pending regulatory approval, we intend to conduct an initial launch, combined with customer support and stabilization, or hypercare, of the initial MosaiQ IH Microarray and initial MosaiQ SDS Microarray into the European donor testing market (in each case, with the MosaiQ Instrument). We plan to follow this initial launch with: (i) a second expanded MosaiQ IH Microarray comprising an expanded antigen typing panel for the donor testing market; (ii) a third MosaiQ IH Microarray comprising the extended antigen typing panel and an expanded antibody detection panel for the patient testing market, which will be commercialized by our commercial partner Ortho; and (iii) an expanded MosaiQ SDS Microarray incorporating assays for the detection of CMV; Syphilis; Hepatitis B, or HBV, comprising HBV Surface Antigen and HBV Core Antibody; Hepatitis C, or HCV; human immunodeficiency virus, or HIV, comprising HIV Type 1 and HIV Type 2; Human T-Lymphotropic Antibodies, or HTLV; and Chagas disease.

In Europe, the MosaiQ Instrument and the initial MosaiQ IH Microarray have received, and the remaining MosaiQ Microarrays will be subject to CE Marking. In the United States, the FDA has indicated to us that the MosaiQ IH Microarray will be subject to a biologics license application, or BLA, and the MosaiQ instrument will be subject to a 510(k) filing. The initial MosaiQ SDS Microarray, comprising tests for CMV and Syphilis, will be subject to a 510(k) filing, while the expanded MosaiQ SDS Microarray will be subject to BLA approval. The MosaiQ Instrument is expected to be classified as a Class II medical device.

In April 2019, we received CE Marking approval for the initial MosaiQ IH Microarray in Europe. We have also completed field trials for the initial MosaiQ SDS Microarray in Europe. We plan to submit an application for marketing clearances for the initial MosaiQ SDS Microarray in June 2019 and expect to obtain market clearance by the end of fiscal year 2020. Field trials in the United States for the expanded MosaiQ IH Microarray and the initial MosaiQ SDS Microarray are expected to commence in 2019, with regulatory submissions planned to be filed shortly after completion of the field trials to obtain required marketing clearances in the United States. The results of the expanded MosaiQ IH Microarray field trial in the United States will also be used as the basis for further field trials and to obtain marketing clearances for this product in Europe. Field trials for the expanded MosaiQ SDS Microarray are expected to be completed in 2019 in Europe and the United States.

Hypercare care launch of MosaiQ will commence in Europe following receipt of CE Marking for the MosaiQ SDS Microarray. We also anticipate commercial launch of the expanded MosaiQ IH Microarray in Europe following a regulatory approval, based upon the results of the US and further European field trials, which is expected to occur later in 2019.

In addition, we intend to continue:

- to engage and collaborate with our key potential customers on the functionality of the MosaiQ system;
- our dialogue with regulators to obtain required regulatory licenses and clearances;
- to 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
- 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 have obtained FDA approvals to sell 64 reagent products in the United States. Through this 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 blood group 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 other 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) blood group antibodies, such as Anti-A and Anti-B; (ii) unexpected 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 and antibodies present in donor and patient blood prior to transfusion. If a donor's red blood cells contain antigens that are recognized by and react with existing blood group antibodies in the patient's plasma, the transfused red blood cells could be destroyed in a potentially life-threatening reaction. The identification of blood group antigens on donor and patient red blood cells is typically referred to as blood typing or basic antigen typing, with a more comprehensive characterization being referred to as extended antigen typing. The identification of blood group antibodies in plasma is typically referred to as antibody identification.

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

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

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

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

Donor blood will typically be subject to a basic antigen typing and an antibody screen. Clinicians will request specific antigen negative donor blood for patients with one or more blood group antibodies. In this instance, multiple donor units will be selected from inventory by the donor collection agency and subjected to an extended antigen typing procedure to identify 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 and patient blood through extended antigen typing prior to transfusion, although the time and expense required to undertake such procedures is currently prohibitive. As a consequence, extended antigen typing is only undertaken as needed (i.e., where the patient has a specific antibody) on a small percentage of donor units. Extended antigen typing for patients is also typically undertaken only in patients expected to be chronically transfused.

#### **Disease Screening**

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

Serological and molecular disease screening is already largely automated. However, it is typically undertaken using instrument platforms that are not integrated with commonly used blood grouping instruments.



## **Donor Testing**

In the developed world, the testing of donated blood is primarily completed by donor collection agencies. In the United States, following the merger of the testing laboratory operations of the American Red Cross (or ARC) with Creative Testing Solutions (or CTS), effective on January 1, 2018, one organization tests approximately 75% of the U.S. blood supply. Throughout Western Europe, Japan, Australia and Canada, national collection agencies, or a small number of regional collection agencies, typically collect and test all donated blood. Currently, donor testing laboratories must adopt multiple instrument platforms, as well as undertake complex manual testing procedures for extended antigen typing or antibody identification, to complete the required testing for donated blood. Maintaining multiple instrument platforms requires complex quality control and assurance procedures, along with costly service and support infrastructures.

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

## **Patient Testing**

Patients are typically blood grouped in hospitals. Large-to-medium-sized 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 have initially developed 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 have initially developed MosaiQ to:

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

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

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 multiplex testing microarrays for use on a high-throughput instrument, the MosaiQ Instrument. Through miniaturization, we plan to combine a full portfolio of existing serological tests on two distinct microarrays for use on MosaiQ – one for blood grouping or immunohematology (or IH) and one for serological disease screening (or SDS). We are also developing a third microarray for molecular disease screening (or MDS). We expect there to be multiple variants of each microarray depending upon the stage of development and the end markets in which we expect the MosaiQ Microarrays will be adopted.

In a donor testing environment, the MosaiQ IH Microarray and the MosaiQ SDS Microarray have been designed to run simultaneously, utilizing the same donor sample and the same MosaiQ Instrument. The MosaiQ MDS Microarray would also be utilized in a donor testing environment. In a patient testing environment, only MosaiQ IH Microarrays would be utilized.

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

The MosaiQ SDS Microarray has been designed to incorporate all tests required to meet current regulatory requirements for serological disease screening of donor blood and source plasma in the markets in which we intend to operate. Initially we will include tests to screen serologically for Syphilis and CMV, and subsequently in the expanded MosaiQ SDS microarray, we plan to include additional tests for HBV, HCV, HIV, HTLV and Chagas disease. The MosaiQ SDS Microarray has additional capacity to incorporate further serological disease screening tests should it be necessary in the future.

The MosaiQ MDS Microarray is being designed to incorporate all mandated tests required to meet current regulatory requirements for molecular disease screening for donor blood and source plasma in the markets in which we intend to operate. We plan to include molecular tests to screen for HBV, HCV, HIV, West Nile virus and Zika.

MosaiQ Microarrays are manufactured using a novel, patented printing technology we have further developed with TTP plc, or TTP, a leading European technology development company. This print technology enables us to industrialize the manufacture of MosaiQ Microarrays. We have an exclusive license for the use of this technology in our fields of use and we are not aware of any alternative technology suitable and commercially available for this purpose.

We have developed a high-throughput, floor standing MosaiQ Instrument for use by both donor collection agencies and medium to large-sized hospitals. The MosaiQ Instrument has been designed to process up to 3,000 microarrays per day (assuming three eight-hour shifts), giving a capacity to test up to 1,500 donor samples (utilizing a MosaiQ IH Microarray and a MosaiQ SDS Microarray) or 3,000 patient samples (utilizing MosaiQ IH Microarrays only). The MosaiQ Instrument can complete the comprehensive characterization of donor or patient blood in less than 35 minutes and has the capability to prioritize urgent patient sample testing, commonly referred to as STAT testing.

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

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. We took delivery of the first commercially ready MosaiQ Instrument in the fourth calendar quarter of 2017.

We are also collaborating with key potential donor and patient testing customers on the development of MosaiQ. This group includes the ARC and CTS, along with several other major hospitals, donor collection organizations and reference laboratories.

#### **Our Conventional Reagent Business**

We have over 30 years of experience in the development, manufacturing and commercialization of conventional reagent products for blood grouping. Our conventional reagent products, which are branded as Alba by Quotient, 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 new Allan Robb Campus (ARC) facility located near Edinburgh, Scotland 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. During 2018, we relocated our operations to the ARC facility which was completed in January 2018. The validation and regulatory approval of the ARC facility was completed on time which allowed us to vacate our previous facility in January 2019.

#### **Our Customers**

In the United States, we currently offer directly to our customers a portfolio of 64 conventional reagent products focused on blood grouping and we have 3 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 905 hospitals, donor collection agencies and independent testing laboratory customers throughout the United States. Global direct sales, including sales to distributors, accounted for 29% of our product sales in the years ended March 31, 2019 and 2018.

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 71% of product sales in the years ended March 31, 2019 and 2018. 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 60% and 61% of our product sales in the years ended March 31, 2019 and 2018, respectively. We are currently developing a range of rare antisera products for use on Ortho's instrument platforms. Several of these products have now received CE Marking for sale in Europe and have been approved for sale in the United States by the FDA. We have filed an updated application with the FDA to cover the use of the products on Ortho's automation platforms in the United States. 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 a facility in Eysins, Switzerland (near Geneva), which is the initial manufacturing site for MosaiQ Microarrays.

#### **TTP plc ("TTP")**

We entered into a master development agreement with TTP to design, build, install and validate the initial manufacturing system for the MosaiQ Microarrays being installed at our Eysins, Switzerland facility. The work under this agreement was completed in 2017 and our Eysins facility was certified in December 2018 under ISO 13485: 2016 for the manufacture of MosaiQ microarrays.

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 Microarrays. The license is for uses that include antigen typing, antibody detection and serological disease 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. Pursuant to this license agreement, we are paying TTP a \$10 million license fee (the TTP License Fee), which is payable in installments through September 30, 2021. We have paid \$3.5 million under this agreement to date, with the balance due in annual instalments which commence in September 2019. 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. 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.

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 Microarrays. 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 ("STRATEC")**

We entered into a development agreement with STRATEC pursuant to which it developed a high-throughput instrument for MosaiQ. The MosaiQ Instrument. The project development timeline ran through the end of 2017. STRATEC's fees under this agreement totaled €13.1 million in aggregate, or \$14.7 million using exchange rates on March 31, 2019.

We have also entered into a manufacturing agreement with STRATEC pursuant to which we will be required to purchase a fixed minimum number of MosaiQ Instruments during the six years following delivery of the first field trial instruments. Our aggregate remaining obligation under this agreement totals €58.0 million, or \$65.0 million using exchange rates on March 31, 2019. 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.

#### **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 OEM 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, 2019, we had 15 employees engaged worldwide in sales, marketing and customer service functions for the conventional reagents business.

### **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 Microarrays within the \$3.3 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 donor disease screening) in territories other than those in which we will commercialize MosaiQ. We will be responsible for the manufacture of all products (instruments, MosaiQ Microarrays 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.

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. A transfer price mechanism for MosaiQ IH Microarrays and MosaiQ SDS Microarrays sold to Ortho has also been established, which will increase as a percentage of net sales based on agreed-upon revenue milestones.

As part of the exclusive sale and distribution rights granted to Ortho for the MosaiQ Instruments and MosaiQ Microarrays (which rights are non-assignable except as provided for in the distribution and supply agreement) we have granted to Ortho licenses and access to other intellectual property, which are necessary or reasonably useful for the sale and distribution of MosaiQ Instruments and MosaiQ Microarrays and which 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 MosaiQ Microarrays, supply serological screening microarrays 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.

### **Research and Development**

Our research and development efforts are focused on the further 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, 2019, we had 206 employees engaged in research and development functions.

### **Customer Funding and Reimbursement**

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

### **Competition**

In the past 10 to 15 years, the transfusion diagnostics market has experienced considerable consolidation, particularly in the United States. Given significant barriers to entry, there are only a small number of vendors currently addressing this market. These vendors can be divided into four groups: (i) those offering instrument platforms for blood grouping and related microarrays, 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 microarrays. A small number of donor collection agencies continue to manufacture a limited range of products, primarily for internal use.

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

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

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

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

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

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 customers 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 MosaicQ Microarrays and instruments. We have entered into an exclusive license with TTP to patented technologies to enable high volume manufacture of MosaicQ Microarrays. 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 MosaicQ instruments, and in the development and manufacture of the MosaicQ instrument, which it will undertake on our behalf. See “Business— MosaicQ Manufacturing and Supply—TTP plc” and “—STRATEC Biomedical AG” for additional information about these agreements. These licenses are material to the development and commercialization of MosaicQ. 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 Canada, Europe, Australia and Japan, which also expire in September 2027.

In February 2014, we filed a new UK patent application providing for a new method for detecting red blood cells, also using MosaicQ. 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.

In January 2018, we filed a provisional U.S. patent application relating to methods and kits for detecting nucleic acids, antigens and antibodies in a sample using a microarray platform, in addition to a method for the amplification of nucleic acids. We made a further filing in December 2018 designating the European Patent Office as the International Searching Authority for this patent application.

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. On May 26, 2017, the European Union adopted a new regulatory framework, the In Vitro Diagnostic Regulation (IVDR 17/746), or IVDR, which replaces the IVD Directive. Our products in the European Union will have to comply with the IVDR requirements after May 26, 2022. Until that time, our products must continue to meet the requirements of IVD Directive for commercialization in the European Union.

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, 2019 and positions, and a brief account of the business experience of the individuals who serve as our executive officers.

Name	Age	Position
Franz Walt	59	Chief Executive Officer
Christopher Lindop	61	Chief Financial Officer
Jeremy Stackawitz	44	President
Edward Farrell	49	President
Roland Boyd	62	Group Financial Controller & Treasurer

*Franz Walt, Chief Executive Officer*

Mr. Walt, joined the Board of Directors in February 2018 and was appointed Interim Chief Executive Officer upon the retirement of Mr. Paul Cowan in March 2018 and was subsequently appointed Chief Executive Officer in May 2018. Mr. Walt served as President of Siemens Healthineers Laboratory Diagnostics, the laboratory diagnostics provider within the healthcare division of Siemens AG, the German based conglomerate, from March 2014 to December 2017. From January 2012 to February 2014, Mr. Walt was the Senior Vice President and head of 'Siemens Healthineers' Diagnostic Division North America. Prior to joining Siemens Healthineers, from June 1989 to November 2011, Mr. Walt served in various capacities at F. Hoffmann-La Roche Ltd., a Swiss based healthcare company that develops diagnostics and therapeutic products, including as Geschäftsführer (CEO) of Roche Diagnostics GmbH in Mannheim from January 2007 to November 2011, and as a board member of the Roche Diagnostic Executive Committee (DiaEC), from November 1998 to December 2006. During his time as a board member of the DiaEC, Mr. Walt served, among other capacities, as President and Consejero Delegado (CEO) of Roche Diagnostics Spain and Regional President for the LATAM Region from October 2004 to December 2006, and as Managing Director of Roche Diagnostics Asia Pacific Pte Ltd. and Regional President for the APAC Region from November 1998 to September 2004. Mr. Walt holds undergraduate degrees in management from the IMAKA Institute of Management in Zürich, and in marketing from the Swiss Institute of Economics in Zürich, and an MBA from City University of Seattle.

*Christopher Lindop, Chief Financial Officer*

Christopher Lindop joined us in February 2017 and serves as our Chief Financial Officer. Mr. Lindop previously served as chief financial officer from January 2007 until June 2016 and as executive vice president of business development from August 2007 until May 2016 of Haemonetics Corporation (NYSE:HAE), a global leader in blood processing technology. From September 2003 to December 2006, he served as chief financial officer of Invemess Medical Innovations, Inc., a global developer, manufacturer and marketer of medical diagnostic products. From June 2002 to September 2003, he served as an audit partner with the Boston office of Ernst & Young LLP, an accounting firm. From 1991 to 2002, he served as an audit partner with the Boston office of Arthur Andersen LLP, an accounting firm. In addition, Mr. Lindop served as a director of Parexel International Corporation (NASDAQ: PRXL) from 2006 until its sale in 2017, where he acted as chairman of the audit and finance committee and as a member of the nominating and governance committee. He holds a B.A. in Business from the University of Strathclyde (Scotland).

*Jeremy Stackawitz, President*

Jeremy Stackawitz joined us in March 2009 and serves as one of our two Presidents. Mr. Stackawitz has over 18 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 microarrays. 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 Barloworld 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.



*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, 2019, we had 410 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](http://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, our filings with the SEC may be accessed through the SEC's website at [www.sec.gov](http://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 28 Esplanade, St Helier, JE2 3QA, Jersey, Channel Islands. Our agent for service of process is our wholly owned U.S. subsidiary, Quotient Biodiagnostics, Inc., 301 South State Street, Suite S-204, Newtown, Pennsylvania 18940. We were incorporated in Jersey, Channel Islands in 2012. Our principal executive offices are located at B1, Business Park Terre Bonne, Route de Crassier 13, 1262 Eysins, Switzerland, and our telephone number is 011-41-22-716-9800. Our website address is [www.quotientbd.com](http://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, 2019, we had an accumulated deficit of \$381.0 million. We expect our operating losses to continue for at least the next fiscal year as we continue our investment in the development and commercialization of MosaiQ. Because of the numerous risks and uncertainties associated with developing and commercializing MosaiQ and the other products we may develop, we are unable to predict the magnitude of any future operating losses or if or when we will become profitable. 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. Even if we achieve profitability, we may not be able to sustain it.

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

We expect to fund our operations in the near-term, including the continued development of MosaiQ to commercialization, from a combination of funding sources, including with existing cash and short-term investment balances, and the issuance of new equity, debt or other securities. Our ability to raise additional capital may be significantly affected by general market conditions, the market price of our ordinary shares, our financial condition, uncertainty about the future commercial success of MosaiQ, regulatory developments, the status and scope of our intellectual property, any ongoing litigation, our compliance with applicable laws and regulations and other factors, many of which are outside our control. Furthermore, the indenture governing the Secured Notes contains limitations on our ability to incur debt and issue preferred and/or disqualified stock. Accordingly, we cannot be certain that we will be able to obtain additional financing on favorable terms or at all. 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, including a decline in the trading price of our ordinary shares. Any additional equity financings could result in additional dilution to our then existing shareholders. In addition, we may enter into additional financings that restrict our operations or adversely affect our ability to operate our business and, if we issue equity, debt or other securities to raise additional capital, the new equity, debt or other securities may have rights, preferences and privileges senior to those of our existing shareholders.

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

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

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

Our future revenue growth and profitability will substantially depend on our ability to successfully commercialize MosaiQ. 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, 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 the MosaiQ Microarrays;
- the occurrence of unforeseen technical difficulties associated with the operation of the manufacturing system for the MosaiQ Microarrays;
- the occurrence of unforeseen technical difficulties associated with the manufacture or operation of the MosaiQ Instrument;
- the occurrence of unforeseen technical difficulties in the design or development of software and the integration of the MosaiQ Microarrays, the MosaiQ 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 the commercialization of MosaiQ would provide others with additional time to commercialize competing products, 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 MosaiQ IH Microarrays and traditional 510(k) clearances for the instrument and the initial MosaiQ SDS Microarray, comprising two tests, CMV and syphilis. The MosaiQ SDS II Microarray, 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 Microarrays 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.

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 performance evaluation studies may not be replicated in later field trial studies. 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.

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

While we have developed the manufacturing system for MosaiQ Microarrays, there can be no assurance that we will be able to manufacture MosaiQ Microarrays at a scale that is adequate for our increasing commercial needs. We may face significant or unforeseen difficulties in manufacturing the MosaiQ Microarrays, 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 Microarray 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 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 Microarrays to more substantive commercial scale. In the event our MosaiQ Microarrays cannot be manufactured in sufficient commercial quantities, market acceptance of MosaiQ could be harmed, our prospects could be significantly impacted and our financial prospects would be materially harmed.

***We cannot accurately predict the volume or timing of any future sales for MosaiQ, making the timing of any such revenues difficult to predict.***

Our limited commercialization experience makes it difficult to evaluate our business and predict our prospects. We may be faced with lengthy customer evaluation and approval processes associated with MosaiQ. Consequently, we may incur substantial expenses and devote significant management effort and expense in developing customer adoption of MosaiQ, which may not result in revenue generation. As such, we cannot accurately predict the volume or timing of any future sales for MosaiQ.

***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 many 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, Danaher, Abbott and Roche, 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;
- our 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, and we may enter into additional distribution or sales arrangements in the future that may subject us to similar risks.***

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 and donor testing markets not covered by Quotient. 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.

We may also enter into additional distribution or sales arrangements to commercialize MosaiQ in other markets. To the extent that we enter into other distribution or sales arrangements, our product revenue is likely to be lower than if we directly market or sell MosaiQ. In addition, any revenue we receive will depend in whole or in part upon the efforts of third parties, which may not be successful and will generally not be within our control. If we are not successful in commercializing MosaiQ through collaborations with one or more third parties, our future product revenue will suffer and we may incur significant additional losses.

***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.

***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 71% of our total revenues and product sales to Ortho accounted for 60% of our total revenues in the year ended March 31, 2019. 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 conventional reagent 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 in our conventional reagent business may negatively impact our profitability.***

Gross margins on our conventional reagent products vary depending upon the product, with whole blood control products, rare antibodies and reagent red blood cell 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 or redeploy 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 microarrays for blood grouping. We believe our principal competitors in the transfusion diagnostics market are Ortho, Immucor, Bio-Rad, Grifols, Danaher, Abbott and Roche.

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 many 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 microarrays 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 may face increased competition in the future if existing companies and competitors develop new or improved products and if 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 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 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 any of our manufacturing facilities become unavailable or inoperable, we will be unable to produce and ship many of our products.***

All our conventional reagent products are currently produced in our ARC facility located near Edinburgh, Scotland. While we believe we have reliable suppliers of raw materials, our reagent production is highly dependent on the uninterrupted and efficient operation of our ARC facility and we currently have no alternative manufacturing capabilities qualified. Therefore, if a catastrophic event occurred at our ARC 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 and other regulatory authorities. 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. 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 ARC 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.

We have leased a manufacturing facility in Eysins, Switzerland, which is presently the principal manufacturing site for MosaiQ Microarrays and we currently have no alternative manufacturing capabilities. Therefore, if a catastrophic event occurred at the Eysins, Switzerland facility, such as a fire or contamination, we would not be able to produce MosaiQ Microarrays until the manufacturing portion of the facility was restored and cleared by the FDA and other regulatory authorities. 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. In addition, we are currently discussing with the landlord the extension of the lease for this facility, which currently expires on March 15, 2020. If we are unable to extend the lease on favorable terms or at all, it may adversely impact our MosaiQ related operations.

***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 while the costs of MosaiQ development are payable mainly in Swiss Francs. As a result, fluctuations in foreign currency exchange rates against the U.S. Dollar could impact our financial results adversely. A significant percentage of our future costs will be incurred in international locations.

Engaging in international business also involves many 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 covenants and other provisions that may limit our operating flexibility.***

We have \$145.0 million aggregate principal amount of the Secured Notes outstanding. The Secured Notes are secured by substantially all of our property and assets (subject to certain exclusions). The indenture governing the Secured Notes contains certain restrictive covenants that limit our ability to incur debt, issue preferred and/or disqualified stock, pay dividends, repurchase shares and make certain other restricted payments, prepay, repurchase or redeem subordinated debt, merge, amalgamate or consolidate with other companies, engage in certain transactions with affiliates and make investments other than those permitted by the indenture. We therefore may not be able to engage in any of the foregoing transactions unless we obtain the consent of the note holders or redeem all the Secured Notes that are then outstanding. There is no guarantee that we will be able to generate sufficient cash flow or sales to pay the principal and interest under the Secured Notes. Furthermore, there is no guarantee that future working capital, borrowings or equity financing will be available to repurchase, redeem or otherwise refinance the Secured Notes.

In addition, upon the occurrence of certain change of control events and, subject to certain conditions, certain asset sales events, holders of the Secured Notes may require us to repurchase for cash all or part of their Secured Notes at a repurchase price equal to 101.0% or 100.0%, respectively, of the principal amount of the Secured Notes to be repurchased, plus accrued and unpaid interest to the date of repurchase. Furthermore, 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 repurchase the Secured Notes or redeem the preference shares under such circumstances.

***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 product liability insurance that we believe 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. If 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. If 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.

***We could experience a breach in the confidentiality of the information we hold or of the security of our computer systems***

We operate large and complex computer systems that contain significant amounts of client data. As a routine element of our business we collect and retain substantial amounts of data pertaining to the work we undertake for customers. Unauthorized third parties could attempt to gain entry to such computer systems for the purpose of stealing the data or disrupting the systems. We believe we have taken appropriate measures to protect them from intrusion, and we continue to improve and enhance our systems in this regard (including how we process and report any breaches), but in the event we are unsuccessful we could suffer significant harm. Our contracts with our customers typically contain provisions that require us to keep confidential any information generated from our work. In the event that the confidentiality of such information was compromised, we could suffer significant harm.

We are also required to comply with the data privacy and security laws in several jurisdictions. For example, we are required to comply with the European Union (EU) General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. GDPR extends the geographical scope of European Union data protection law to non-E.U. entities under certain conditions, tightens existing European Union data protection principles, creates new obligations for companies and new rights for individuals, and imposes enhanced penalties for non-compliance. The potential for fines and penalties in the event of a violation of GDPR may have a significant adverse impact on our business and operations. We have made changes to, and continue to make enhancements of, our business practices to help attain compliance with these evolving and complex regulations.

***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 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. 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, but none of these agreements guarantees the service of the individual for a specified period. 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 able 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 Microarrays 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, the ownership or control of intellectual property developed during the collaboration or the scope of our or our collaborators' other rights or obligations related to development or commercialization activities. 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

*Recent global economic and political conditions could result in significant changes to legislation, government policies, rules and regulations, which may have a material adverse effect on our business.*

The impact of recent political and economic developments in the United States, the United Kingdom and Europe, including the election of Mr. Donald Trump as president of the United States and the referendum in the United Kingdom in which voters approved an exit from the European Union, commonly referred to as “Brexit,” are uncertain. These political and economic developments could result in changes to legislation or reformation of government policies, rules and regulations pertaining to the U.S. healthcare system, tax and trade. Such changes 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.

Efforts to repeal and replace the U.S. Patient Protection and Affordable Care Act (or the PPACA) have been ongoing since the 2016 election, but it is unclear if these efforts will be successful. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay, circumvent or loosen the implementation of certain provisions mandated by the PPACA or otherwise circumvent some of the requirements for health insurance mandated by the PPACA. In addition, as part of the December 2017 Tax Cuts and Jobs Act, the “individual mandate,” which required individuals to purchase insurance, was repealed. In addition, there are continuing legal challenges to the PPACA and, due to the current Republican Senate/Democratic House split in Congress as a result of the 2018 U.S. midterm elections, it is unlikely that a legislative solution would be reached to address any such challenges. The PPACA significantly impacted the pharmaceutical and medical device industries and clinical laboratories, and the repeal, replacement or modification of the PPACA, or other legislative or regulatory actions, could meaningfully further 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.

Our conventional reagent products are manufactured in Scotland and our MosaiQ Instruments and Microarrays will be manufactured in Germany and Switzerland, respectively. There have been public announcements by members of the U.S. Congress, President Trump and his administration regarding the possible implementation of a border tax, tariff or increase in custom duties on products manufactured outside of and imported into the United States, as well as the renegotiation of U.S. trade agreements, and, in March 2018, President Trump issued two proclamations imposing tariffs on imports of certain steel and aluminum products. The implementation of a border tax, tariff or higher customs duties on our products imported into the United States, or any potential corresponding actions by other countries in which we do business, could negatively impact our financial performance.

As a result of the Brexit referendum, the United Kingdom and the European Union continue to be involved in a negotiation process to determine the future terms of the United Kingdom's relationship with the European Union, and it appears likely that these negotiations will continue to be lengthy. For example, while the U.K. government and the European Union had negotiated an agreement by which the United Kingdom would withdraw from the European Union and the European Union had approved this withdrawal agreement, the British Parliament has subsequently rejected the withdrawal agreement several times. The date for the United Kingdom's exit from the European Union, which was originally scheduled for March 29, 2019, has been postponed to October 31, 2019. While we believe we have developed plans to manage the risk to our business and operations, including in the event that the United Kingdom exits without any agreement on its future relationship with the European Union, it is unknown what the final terms of the relationship will be. If no agreement can be reached and the United Kingdom leaves the European Union with no agreement, there will be a period of considerable uncertainty, particularly in relation to the U.K. financial and banking markets, the regulatory process in Europe and movement of goods and people between the United Kingdom and European Union. As a result of this uncertainty, financial markets could experience volatility, which could adversely affect the market price of our ordinary shares. It is also possible that, even if there is an agreement, there will be greater restrictions and transportation delays on imports and exports between the United Kingdom and European Union countries and increased regulatory complexities, which could result in delays and increased expenses relating to the regulatory approval of our products. In addition, depending on the terms of Brexit, the United Kingdom could lose the benefits of global trade agreements negotiated by the European Union on behalf of its members, which may result in increased trade barriers which could make our doing business worldwide more difficult. Furthermore, currency exchange rates in the pound sterling and the euro with respect to each other and the U.S. dollar have already been adversely affected by Brexit. Should this foreign exchange volatility continue, it could cause volatility in our financial results.

***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.

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 modify or 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 regarding compliance with current good manufacturing practices at one or more of our manufacturing facilities.

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 act 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.***

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.

Obtaining FDA and other regulatory clearances or approvals for MosaiQ and our newly developed conventional reagent products can be time-consuming, expensive and uncertain. It can take from several months to several years from the date of submission of the application, and generally requires detailed and comprehensive scientific and clinical data. As with all blood transfusion products, the FDA and other regulatory authorities reserve the right to redefine the regulatory path at the time of submission or during the review process, and could require a more burdensome approach than we currently anticipate. Notwithstanding the time and expense, 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. 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, the collection and use of health data in the European Union is governed by the recently-enacted GDPR. The GDPR may increase our responsibility and liability in relation to personal data that we process and we may be required to put in place additional mechanisms ensuring compliance with the GDPR. This may be onerous and if our efforts to comply with GDPR or other applicable European Union laws and regulations are not successful, we may be subject to substantial fines and other administrative penalties, which could adversely affect our business in the European Union.

Additionally, under some environmental laws and regulations, we could be held responsible for costs relating to any contamination at our past or present facilities and at third-party waste disposal sites even if such contamination was not caused by us. A failure to comply with current or future environmental laws and regulations, including the failure to obtain, maintain or comply with any required permits, could result in severe fines or penalties. Any such expenses or liability could have a significant negative impact on our business, results of operations and financial condition. In addition, we may be required to incur significant costs to comply with regulatory requirements in the future.

***Our relationships with customers are subject to applicable anti-kickback, fraud and abuse and other domestic healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.***

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

The federal healthcare anti-kickback statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made under federally funded healthcare programs such as Medicare and Medicaid. This statute has been broadly interpreted to apply to manufacturer arrangements with prescribers, purchasers and formulary managers, among others. Several other countries, including the United Kingdom, have enacted similar anti-kickback, fraud and abuse, and healthcare laws and regulations.

The federal False Claims Act imposes criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement material to a false or fraudulent action or improperly avoiding, decreasing or concealing an obligation to pay money to the federal government.

HIPAA imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program and also imposes obligations, including mandatory contractual terms, with respect to safeguarding the privacy, security and transmission of individually identifiable health information. In addition, HIPAA created criminal liability for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services.

The federal Physician Payment Sunshine Act requirements under the PPACA require manufacturers of drugs, devices, biologics and medical supplies to report to HHS information related to payments and other transfers of value made to or at the request of covered recipients, such as physicians and teaching hospitals, and physician ownership and investment interests in such manufacturers. Payments made to physicians and research institutions for clinical trials are included within the ambit of this law. Certain state laws and regulations also require the reporting of certain items of value provided to health care professionals.

Analogous state laws and regulations, such as state anti-kickback and false claims laws, may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. We may be subject to qui tam litigation brought by private individuals on behalf of the government under the 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 many 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.

#### **Risks Related to Intellectual Property**

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

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

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

The extent to which the patent rights of life sciences companies effectively protect their products and technologies is often highly uncertain and involves complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the proper scope of allowable claims of patents held by such companies has emerged to date in the United States. Various courts, including the U.S. Supreme Court, have rendered decisions that impact the scope of patentability of certain inventions or discoveries relating to diagnostics tests or genomic diagnostics. These decisions generally stand for the proposition that inventions that recite laws of nature are not themselves patentable unless they have sufficient additional features that provide practical assurance that the processes are genuine inventive applications of those laws rather than patent drafting efforts designed to monopolize a law of nature itself. What constitutes a "sufficient" additional feature for this purpose is uncertain. While we do not generally rely on gene sequence patents, this evolving case law in the United States may adversely impact our ability to obtain new patents and may facilitate third-party challenges to our existing owned and exclusively licensed patents.

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

- the inventor(s) named in one or more of our patents or patent applications might not have been the first to have made the relevant invention;
- the inventor (or his assignee) might not have been the first to file a patent application for the claimed invention;
- others may independently develop similar or alternative products and technologies or may successfully replicate our product and technologies;
- it is possible that the patents we own, or in which we have exclusive license rights may not provide us with any competitive advantages or may be challenged by third parties and found to be invalid or unenforceable;
- any patents we obtain or exclusively license may expire before, or within a limited 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 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 Microarrays 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 TTP, to use patented technologies to enable high volume manufacturing of MosaiQ Microarrays. 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 that were 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 Microarrays 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 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 commercial success depends significantly on our ability to operate without infringing the patents and other intellectual property rights of third parties. Other entities may have or obtain patents or other intellectual property rights that could limit our ability to manufacture or commercialize MosaiQ, or may claim that our research, development and commercialization activities infringe patents or other intellectual property rights owned by them 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 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 because 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 Ordinary Shares**

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

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including (1) not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act, (2) reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements and (3) exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company until March 31, 2020, 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 issue more than \$1.0 billion in non-convertible debt during any three-year period before that time, we would cease to be an emerging growth company immediately.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until 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.

In addition, we are also a smaller reporting company, as defined in Rule 12b-2 under the Exchange Act. In the event that we are still considered a smaller reporting company at such time as we cease being an emerging growth company, the disclosure we will be required to provide in our SEC filings will increase, but will still be less than it would be if we were not considered either an emerging growth company or a smaller reporting company.

Effective on September 10, 2018, Rule 12b-2 of the Exchange Act defines a “smaller reporting company” as an issuer that is not an investment company, an asset-backed issuer or a majority-owned subsidiary of a parent that is not a smaller reporting company and that:

- (1) had a public float of less than \$250 million; or
- (2) had annual revenues of less than \$100 million during the most recently completed fiscal year for which audited financial statements are available and either had no public float or a public float of less than \$700 million.

In the case of reporting companies like us, public float is calculated as of the last business day of the issuer's most recently completed second fiscal quarter and calculated by multiplying the aggregate world wide number of shares of its voting and non-voting common equity held by non affiliates by the price at which the common equity was last sold, or the average.

Similar to emerging growth companies, smaller reporting companies are able to provide simplified executive compensation disclosures in their filings, and have certain other decreased disclosure obligations in their SEC filings, including, among other things, being required to provide only two years of audited financial statements in annual reports.

We cannot predict if investors will find our ordinary shares less attractive because we may rely on these exemptions. If some investors find our ordinary shares less attractive as a result, there may be a less active trading market for our ordinary shares and the price of our ordinary shares may be more volatile.

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

Like other emerging life sciences companies, the market price of our ordinary shares is likely to be volatile. The factors below may also have a material adverse effect on the market price of our ordinary shares:

- fluctuations in our results of operations;
- delays in the planned commercialization of MosaiQ;
- speed and timing of adoption of MosaiQ by key target customers;
- our ability to enter new markets;
- negative publicity;
- changes in securities or industry analyst recommendations regarding our company, the sectors in which we operate, the securities market generally, conditions in the financial markets and the perception of our ability to raise additional funding;
- regulatory developments affecting MosaiQ or our industry, including announcement of new adverse regulatory decisions affecting our industry or 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 ordinary shares subject to such restrictions; and
- sales or perceived sales of additional ordinary shares.

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

***If securities analysts do not continue to cover our ordinary shares or publish unfavorable research or reports about our business, this may have a negative impact on the market price of our ordinary shares.***

The trading market for our ordinary shares depends on the research and reports that securities analysts publish about our business and our company. We do not have any control over these analysts. There is no guarantee that securities analysts will continue to cover our ordinary shares. If securities analysts do not cover our ordinary shares, the lack of research coverage may adversely affect the market price of our ordinary shares. If our shares are the subject of an unfavorable report, our share price and trading volume would likely decline. If one or more of these analysts ceases to cover our company or fails to publish regular reports on our company, we could lose visibility in the financial markets, which could cause our share price or trading volume to decline.

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

Additional sales of our ordinary shares in the public market, and in particular sales by our directors, executive officers and principal shareholders, or the perception that these sales could occur, could cause the market price of our ordinary shares to decline. We had outstanding 65,900,447 ordinary shares as of March 31, 2019, of which approximately 57,440,009 ordinary shares were sold or issued pursuant to effective registration statements or resold pursuant to Rule 144 under the Securities Act, or Rule 144, or are registered for public resale under an effective registration statement under the Securities Act and are freely transferable without restriction or additional registration under the Securities Act. Approximately 8,460,438 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, 2019, 175,525 ordinary shares were subject to outstanding warrants at a weighted average exercise price of \$13.67 per share and 1,936,397 ordinary shares were subject to outstanding options at a weighted exercise price of \$7.77 per share. To the extent any of these shares are sold into the market, particularly in substantial quantities, the market price of our ordinary shares could decline.

***We have never paid cash dividends and do not intend to pay cash dividends on our ordinary shares in the foreseeable future.***

We have never paid dividends on ordinary shares and do not anticipate paying any cash dividends on our ordinary shares in the foreseeable future. In addition, the indenture governing the Secured Notes contains covenants that limit our ability to pay dividends on our ordinary shares. 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 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 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 Board of Directors, delaying or preventing a change in our control or otherwise discouraging a potential acquirer from attempting to obtain control of us, which in turn could have a material and adverse effect on the fair market value of our ordinary shares.

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

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

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

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

Our ordinary shares are listed on Nasdaq. However, we cannot ensure that we will be able to satisfy the continued listing standards of Nasdaq going forward. If we cannot satisfy the continued listing standards going forward, The Nasdaq Stock Market may commence delisting procedures against us, which could result in our ordinary shares being removed from listing on Nasdaq. If our ordinary shares were to be delisted, the liquidity of our ordinary shares could be adversely affected and the market price of our ordinary shares could decrease. Delisting could also adversely affect the ability of a holder of our ordinary shares to trade or obtain quotations on our ordinary shares because of lower trading volumes and transaction delays.

These factors could contribute to lower prices and larger spreads in the bid and ask price for our ordinary shares. You may also not be able to resell your ordinary shares at or above the price you paid for such ordinary shares or at all.

***The dilutive effect of our warrants and options 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, 2019, there were outstanding warrants to purchase (i) 64,000 of our ordinary shares at an exercise price of \$9.375 per share and (ii) 111,525 of our ordinary shares at an exercise price of \$16.14 per share. In addition, as of March 31, 2019, there were outstanding options to purchase 1,936,397 ordinary shares at a weighted average exercise price of \$7.77 per share. These warrants and options are likely to be exercised if the market price of our ordinary shares equals or exceeds the applicable warrant's or option's exercise price. To the extent such warrants and options are exercised, additional ordinary shares will be issued, which would dilute the ownership of existing shareholders.

#### **Risks Related to Being a Jersey, Channel Islands Company Listing Ordinary Shares**

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

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

***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.

***Recently adopted tax legislation in Jersey, Channel Islands may impact our operations.***

Jersey has enacted the Taxation (Companies - Economic Substance) (Jersey) Law 2019, which we refer to as the "Substance Law". The Substance Law applies to financial periods of Jersey resident bodies corporate starting on or after January 1, 2019. The Substance Law is administered by the Jersey Comptroller of Taxes, who has produced guidance as to its application.

The Substance Law applies to Jersey tax resident companies that carry on banking, insurance, fund management, financing and leasing, headquarters, shipping, and holding company or intellectual property activities and are in receipt of gross income arising from such activities in any relevant financial period. It imposes certain requirements including that such companies be directed and managed in Jersey, have core income generating activities in Jersey and have an adequate level of employees, expenditures and premises in Jersey.

Having taken advice, we do not believe that the Substance Law presently applies to our company or our subsidiaries that are tax resident in Jersey. However, we cannot guarantee that we will not be required to implement changes to comply with the Substance Law in the future and thereby incur unexpected expenses or otherwise be subject to certain sanctions if we were to fail to comply.

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

A non-U.S. corporation will be a passive foreign investment company, or PFIC, for any taxable year in which (1) at least 75% of its gross income is passive income or (2) at least 50% of the value (determined on a quarterly basis) of its assets is attributable to assets that produce or are held for the production of passive income. Our status as a PFIC depends on certain facts outside of our control and the application of U.S. federal income tax rules that are not entirely clear. Accordingly, there can be no assurance that we will not be classified as a PFIC for our current taxable year or any future taxable year. If we are treated as a PFIC for any taxable year during which you hold our ordinary shares, such treatment could result in materially adverse U.S. federal income tax consequences to you if you are a U.S. taxable investor. For example, if we are or become a PFIC, you may become subject to increased tax liabilities under U.S. federal income tax laws and regulations, and will become subject to additional reporting requirements. Although we do not believe we were a PFIC for our taxable year ended March 31, 2019 and do not expect to be a PFIC for the taxable year ending March 31, 2020 or any future taxable year, we cannot assure you that we have not been or will not be a PFIC for any particular taxable year. U.S. investors considering an investment in our ordinary shares are urged to consult their tax advisors regarding our possible status as a PFIC.

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

The United States has enacted rules, commonly referred to as "FATCA," that generally impose a reporting and withholding regime with respect to certain U.S. source payments (including dividends and interest) and certain payments made by entities that are classified as financial institutions under FATCA ("foreign passthru payments"). 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 the second anniversary of the date on which final regulations defining the term "foreign passthru payments" are published in the U.S. Federal Register. Prospective investors should consult their own tax advisors regarding the potential impact of FATCA, including the agreement relating to FATCA between the governments of Jersey and the United States, to an investment in the ordinary shares.

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

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

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 corporate headquarters, including our principal manufacturing site for MosaiQ Microarrays are located in Eysins, Switzerland. Our UK corporate offices and other office facilities, a development laboratory facility and our manufacturing facility for conventional reagent products are located near Edinburgh, Scotland. Our U.S. corporate offices are located in Newtown, Pennsylvania. The table below provides selected information regarding our existing facilities, all of which are leased.

Facility/Use	Location	Size (sq. ft.)		Expiration
		Office	Laboratory	
UK Corporate Offices/Development Laboratory and Conventional Reagents Manufacturing Facility	Edinburgh, Scotland	27,400	59,800	September 30, 2052
Corporate Headquarters and Manufacturing Operations— MosaiQ	Eysins, Switzerland	13,600	31,600	March 15, 2020
U.S. Corporate Offices	Newtown, PA, USA	1,200	—	November 30, 2021
U.S. Direct Sales Operation	Chapel Hill, NC, USA	1,000	—	July 31, 2019
Ireland General Offices	Dublin, Ireland	500	—	March 11, 2020

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. Discussions are underway with the landlord of our facility in Eysins, Switzerland for the extension of the lease beyond March 15, 2020 and we believe that we should be able to obtain such an extension on satisfactory terms.

**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*

Our ordinary shares are traded on the Nasdaq Global Market under the symbol "QTNT". On May 28, 2019, the last reported sale price of our ordinary shares on Nasdaq was \$10.06 per share.

#### *Shareholders*

On May 28, 2019, there were 23 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*

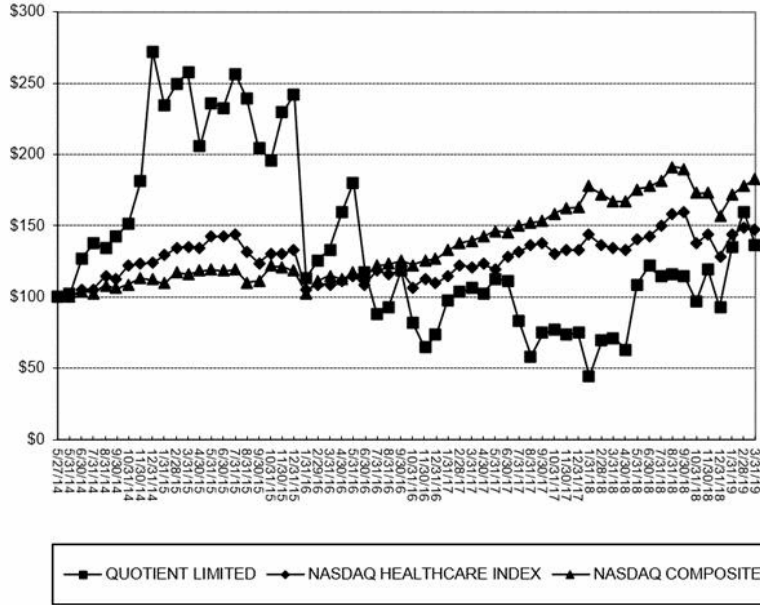
We have never declared or paid cash dividends on our ordinary shares. We currently intend to retain all available funds and any future earnings, if any, to fund the development and expansion of our business and we do not anticipate paying any cash dividends in the foreseeable future. In addition, the indenture governing the Secured Notes contains certain restrictive covenants that limit our ability to pay dividends. 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 (including under the indenture for the Secured Notes), 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 the ordinary shares and warrants comprising the units issued in our initial public offering began trading separately on Nasdaq) through March 31, 2019 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.

which we refer to as

**COMPARISON OF 58 MONTH CUMULATIVE TOTAL RETURN\***  
 AMONG QUOTIENT LIMITED, THE NASDAQ STOCK MARKET COMPOSITE INDEX  
 AND THE NASDAQ HEALTHCARE INDEX



\* \$100 invested on 5/27/14 in stock or index including reinvestment of dividends.  
 58 Months ended March 31, 2019

### Securities Authorized for Issuance Under Equity Compensation Plans

The following table presents certain information about our equity compensation plans as of March 31, 2019:

	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)	2,903,296	\$ 5.18	376,114
Equity compensation plans not approved by shareholders	—	—	—

- (1) Composed of the 2012 Option Plan, pursuant to which 357,651 ordinary shares are issuable upon exercise of outstanding options and rights at a weighted average exercise price of \$1.99, and the 2014 Stock Incentive Plan, pursuant to which 2,545,435 ordinary shares are issuable upon exercise of outstanding options and rights at a weighted average exercise price of \$5.63. At March 31, 2019, 376,114 ordinary shares remain available for future issuance under the 2014 Stock Incentive Plan.

### Recent Sales of Unregistered Securities

Since April 1, 2018, we issued the following securities that were not registered under the Securities Act.

On August 3, 2018, we entered into two subscription agreements: (i) the first, by and between us and Franz Walt, our Chief Executive Officer, pursuant to which Mr. Walt subscribed for, and we agreed to issue, 45,000 ordinary shares at a price of \$7.54 per share (which we refer to as the Subscription Price) (which was equal to the closing bid price of our ordinary shares as reported on the Nasdaq Global Market on August 2, 2018) for aggregate proceeds of \$339,300.00 and (ii) the second, by and between us and Heino von Prondzynski, the Chairman of our board of directors, pursuant to which Mr. von Prondzynski subscribed for, and we agreed to issue, 10,000 ordinary shares at the Subscription Price for aggregate proceeds of \$75,400.00. The subscription shares were sold in reliance upon the exemption from registration provided by Section 4(a)(2) of the Securities Act. Each of Mr. Walt and Mr. von Prondzynski represented in his subscription agreement that he was knowledgeable, sophisticated and experienced in financial and business matters, an accredited investor as defined in Regulation D and that he was acquiring the subscription shares with no present intention of distributing any of such shares or any arrangement or understanding with any other persons regarding the distribution of such shares, and appropriate legends were affixed to the subscription shares. The aggregate gross proceeds were \$0.4 million.

## 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, 2019, 2018 and 2017 and the consolidated balance sheet data as of March 31, 2019 and 2018 have been derived from our audited consolidated financial statements appearing elsewhere in this Annual Report on Form 10-K. The consolidated statement of income data for the year ended March 31, 2016 and 2015 and the consolidated balance sheet data as of March 31, 2017, 2016 and 2015 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,				
	2019	2018	2017	2016	2015
(in thousands, except share and per share data)					
<b>Consolidated statement of loss:</b>					
Revenue:					
Product sales	\$ 28,665	\$ 23,913	\$ 20,127	\$ 18,022	\$ 17,658
Other revenues	469	819	2,100	500	750
<b>Total revenue</b>	<b>29,134</b>	<b>24,732</b>	<b>22,227</b>	<b>18,522</b>	<b>18,408</b>
Cost of revenue	(17,230)	(10,471)	(10,844)	(9,658)	(9,763)
<b>Gross profit</b>	<b>11,904</b>	<b>14,261</b>	<b>11,383</b>	<b>8,864</b>	<b>8,645</b>
<b>Operating expenses:</b>					
Sales and marketing	(8,637)	(7,347)	(5,660)	(3,073)	(2,750)
Research and development, net of government grants	(50,677)	(51,202)	(57,064)	(28,781)	(19,216)
General and administrative expense:					
Compensation expense in respect of share options and management equity incentives	(4,957)	(4,156)	(4,221)	(2,004)	(1,138)
Other general and administrative expenses	(26,588)	(21,544)	(18,497)	(24,094)	(15,255)
Total general and administrative expense	(31,545)	(25,700)	(22,718)	(26,098)	(16,393)
<b>Total operating expense</b>	<b>(90,859)</b>	<b>(84,249)</b>	<b>(85,442)</b>	<b>(57,952)</b>	<b>(38,359)</b>
<b>Operating loss</b>	<b>(78,955)</b>	<b>(69,988)</b>	<b>(74,059)</b>	<b>(49,088)</b>	<b>(29,714)</b>
<b>Other income (expense):</b>					
Interest expense, net	(20,018)	(15,365)	(9,903)	(4,151)	(2,315)
Change in financial liability for share warrants	—	—	—	15,857	(22,966)
Other, net	(6,369)	2,366	(1,107)	3,504	(4,064)
<b>Other income (expense), net</b>	<b>(26,387)</b>	<b>(12,999)</b>	<b>(11,010)</b>	<b>15,210</b>	<b>(29,345)</b>
<b>Loss before income taxes</b>	<b>(105,342)</b>	<b>(82,987)</b>	<b>(85,069)</b>	<b>(33,878)</b>	<b>(59,059)</b>
Provision for income taxes	(44)	649	—	—	—
<b>Net loss</b>	<b>\$ (105,386)</b>	<b>\$ (82,338)</b>	<b>\$ (85,069)</b>	<b>\$ (33,878)</b>	<b>\$ (59,059)</b>
Net loss available to ordinary shareholders					
- basic and diluted	\$ (105,386)	\$ (82,338)	\$ (85,069)	\$ (33,878)	\$ (59,059)
Loss per share - basic and diluted	\$ (1.92)	\$ (2.02)	\$ (3.02)	\$ (1.73)	\$ (4.00)
Weighted-average shares outstanding - basic and diluted					
	54,874,391	40,839,309	28,145,472	19,558,152	14,773,386

	As of March 31,				
	2019	2018	2017	2016	2015
(in thousands)					
<b>Consolidated balance sheet data:</b>					
Cash and cash equivalents	\$ 4,096	\$ 20,165	\$ 4,754	\$ 44,100	\$ 37,525
Short-term investments	90,729	5,669	16,057	—	—
Total assets	177,770	123,841	109,971	119,750	80,204
Long-term debt	121,855	85,063	80,704	27,910	9,853
Total liabilities	176,056	138,472	134,062	73,027	81,819
Total shareholders' funds (deficit)	\$ 1,714	\$ (14,631)	\$ (24,091)	\$ 46,723	\$ (1,615)

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

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

### Overview

We were incorporated in Jersey, Channel Islands on January 18, 2012. On February 16, 2012, we acquired the entire issued share capital of Alba Bioscience Limited (or Alba), Quotient Biodiagnostics, Inc. (or QBDI) and QBD (QS IP) Limited (or QSIP) from Quotient Biodiagnostics Group Limited (or QBDG), our predecessor.

### Our Business

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

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

We currently operate as one business segment with over 400 employees in the United Kingdom, Switzerland and the United States. Our principal markets are the United States, Europe and Japan. Based on the location of the customer, revenues outside the United States accounted for 49%, 48% and 49% of total revenue during the years ended March 31, 2019, 2018 and 2017, respectively.

We have incurred net losses and negative cash flows from operations in each year since we commenced operations in 2007. As of March 31, 2019, we had an accumulated deficit of \$381.0 million. We expect our operating losses will continue for at least the next fiscal year as we continue our investment in the commercialization of MosaiQ. Our total revenue was \$29.1 million for the year ended March 31, 2019, \$24.7 million for the year ended March 31, 2018 and \$22.2 million for the year ended March 31, 2017. Our net loss was \$105.4 million for the year ended March 31, 2019, \$82.3 million for the year ended March 31, 2018 and \$85.1 million for the year ended March 31, 2017.

From our incorporation in 2012 to March 31, 2018, we have raised \$110.8 million of gross proceeds through the private placement of our ordinary and preference shares and warrants, \$181.1 million of gross proceeds from public offerings of our shares and issuances of ordinary shares upon exercise of warrants and \$84.0 million of gross proceeds from the issuance of 12% Senior Secured Notes due 2024 (which we refer to as the Secured Notes).

On June 29, 2018, we issued an additional \$36.0 million aggregate principal amount of the Secured Notes. As referenced above, we previously issued \$84.0 million aggregate principal amount of the Secured Notes on October 14, 2016. On June 29, 2018, we paid \$2.2 million of the net proceeds of the issuance of the additional Secured Notes into the cash reserve account maintained with the collateral agent under the terms of the indenture governing the Secured Notes, which together with the \$5.0 million paid into the cash reserve account on October 14, 2016, brought the total in the cash reserve account to \$7.2 million at March 31, 2019.

In the period between March 31, 2018 and July 31, 2018, 8,414,683 warrants that were previously issued in connection with our October 2017 private placement of ordinary shares were exercised for 8,414,683 ordinary shares at \$5.80 per share, which generated \$48.8 million of proceeds.

On August 3, 2018, we entered into two subscription agreements with Franz Walt, our Chief Executive Officer, and with Heino von Prondzynski, our Chairman, pursuant to which we issued a combined total of 55,000 ordinary shares at a price of \$7.54 per share (which was equal to the closing bid price of our ordinary shares as reported on the Nasdaq Global Market on August 2, 2018) for aggregate proceeds of \$0.4 million.

On December 11, 2018, we completed a public offering of 10,615,385 newly issued ordinary shares at a price of \$6.50 per share which raised \$69 million of gross proceeds before underwriting discounts and other offering expenses.

On December 18, 2018, we completed certain amendments to the indenture governing the Secured Notes. These amendments included a six-month extension of the final maturity of the Secured Notes to April 2024 and a revision of the Secured Notes' principal amortization (previously scheduled to commence semi-annually beginning April 2019) to commence April 2021, in order to better align the maturity and amortization schedule with our financial goals. The revised amortization schedule defers approximately \$39.6 million of principal amortization previously scheduled to occur between April 2019 and April 2021. In addition, the amendments include a one-year extension of the optional redemption call schedule to October 2022. In consideration for the consents to the amendments, we paid to the noteholders a one-time consent payment of \$3.9 million and we issued additional royalty rights to the noteholders, which increased in the aggregate the amount of the royalties payable under the royalty rights that were previously issued by us in connection with the prior issuances of the Secured Notes by 1%, from 2% to 3%, of the aggregate net sales of MosaiQ instruments and consumables in specified markets.

The amendments also increased the aggregate principal amount of Secured Notes that can be issued under the indenture from \$120 million to up to \$145 million following the European CE Marking of our initial MosaiQ IH Microarray. On January 15, 2019 we entered into purchase agreements pursuant to which we agreed to issue and certain purchasers agreed to purchase the additional \$25 million of the Secured Notes. On May 1, 2019 we announced that the CE Mark of our initial MosaiQ IH Microarray had been granted, and, on May 15, 2019, we issued an additional \$25 million of the Secured Notes. We also issued royalty rights to the purchasers representing the right to receive 0.4% of the aggregate net sales of MosaiQ instruments and consumable in specified markets.

As of March 31, 2019, we had available cash, cash equivalents and short-term investments of \$94.8 million and \$7.5 million of restricted cash held as part of the arrangements relating to our Secured Notes and the lease of our property in Eysins, Switzerland.

#### **Revenue**

We generate product sales revenue from the sale of conventional reagent products directly to hospitals, donor collection agencies and independent testing laboratories in the United States, the United Kingdom and to distributors in Europe and the rest of the world, and indirectly through sales to our OEM customers. We recognize revenues in the form of product sales when the goods are shipped. Products sold by standing purchase orders as a percentage of product sales revenue were 68% for the year ended March 31, 2019, 75% for the year ended March 31, 2018 and 76% for the year ended March 31, 2017. We also provide product development services to our OEM customers. We recognize revenue from these contractual relationships in the form of product development fees, which are included in Other revenues. For a description of our revenue recognition policies, see "—Critical Accounting Policies and Significant Judgments and Estimates—Revenue Recognition and Accounts Receivable." In the year ended March 31, 2018, other revenues also included the sale of two MosaiQ instruments to a development partner.

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

#### **Cost of revenue and operating expenses**

Cost of revenue consists of direct labor expenses, including employee benefits, overhead expenses, material costs and freight costs, along with the depreciation of manufacturing equipment and leasehold improvements. Our gross profit represents total revenue less the cost of revenue, gross margin represents gross profit expressed as a percentage of total revenue, and gross margin on product sales represents gross margin excluding other revenues as a percentage of revenues excluding other revenues. We expect our overall cost of revenue to increase in absolute U.S. Dollars as we continue to increase our product sales volumes. However, we also believe that we can achieve efficiencies in our manufacturing operations, primarily through increasing production volumes.

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

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

We expense all research and development costs as incurred, net of government grants received and tax credits. Our UK subsidiary claims certain tax credits on its research and development expenditures and these are included as an offset to our research and development expenses. Our research and development efforts are focused on developing new products and technologies for the global transfusion diagnostics market. We segregate research and development expenses for the MosaiQ project from expenses for other research and development projects. We do not maintain detailed records of these other costs by activity. We are nearing completion of the initial development of MosaiQ and as we move to commercialization, we expect overall research and development expense to decrease.

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

Net interest expense consists primarily of interest charges on our note and loan balances and the amortization of debt issuance costs (which includes amortization of the one-time consent payment of \$3.9 million paid to holders of our Senior Notes in December 2018), as well as accrued dividends on the 7% cumulative redeemable preference shares issued in January 2015. We amortize debt issuance costs over the life of the note or loan and report them as interest expense in our statements of operations. Net interest also includes the expected costs of the royalty rights agreements we entered into in October 2016, June 2018 and December 2018 with the purchasers or holders of the Secured Notes, as applicable. See Note 3 "Debt" and Note 8 "Ordinary and Preference Shares – Preference shares" to our consolidated financial statements included in this Annual Report for additional information.

Other income (expense), net consists primarily of exchange fluctuations. These include realized exchange fluctuations resulting from the settlement of transactions in currencies other than the functional currencies of our businesses. Monetary assets and liabilities that are denominated in foreign currencies are measured at the period-end closing rate with resulting unrealized exchange fluctuations. The functional currencies of our businesses are Pounds Sterling, Swiss Franc and U.S. Dollars depending on the entity. Other income (expense) also includes exceptional costs related to deferred debt issue costs expensed on the repayment of debt facilities and certain other non-recurring items as mentioned below under "—Results of Operations— Comparison of Years ended March 31, 2019 and 2018— Other income (expense)" and "—Results of Operations— Comparison of Years ended March 31, 2018 and 2017— Other income (expense)."

Provision for income taxes in the year ended March 31, 2019 reflected a reduction in the net operating losses available to be carried forward in a subsidiary as a result of the offset of historic tax losses against the profits of this subsidiary. Provision for income taxes in the year ended March 31, 2018 reflected a reduction in the valuation allowance against deferred tax assets in a subsidiary as a result of an improvement in the profitability of this subsidiary.



## Results of Operations

### Comparison of Years ended March 31, 2019 and 2018

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

	Year ended March 31,				Change	
	2019		2018		Amount	%
	Amount	% of revenue	Amount	% of revenue		
	(in thousands, except percentages)					
<b>Revenue:</b>						
Product sales	\$ 28,665	98%	\$ 23,913	97%	\$ 4,752	20%
Other revenues	469	2%	819	3%	(350)	-43%
Total revenue	29,134	100%	24,732	100%	4,402	18%
Cost of revenue	17,230	59%	10,471	42%	6,759	65%
Gross profit	11,904	41%	14,261	58%	(2,357)	-17%
<b>Operating expenses:</b>						
Sales and marketing	8,637	30%	7,347	30%	1,290	18%
Research and development	50,677	174%	51,202	207%	(525)	-1%
General and administrative	31,545	108%	25,700	104%	5,845	23%
Total operating expenses	90,859	312%	84,249	341%	6,610	8%
Operating (loss)	(78,955)	-271%	(69,988)	-283%	(8,967)	13%
<b>Other income (expense):</b>						
Interest expense, net	(20,018)	-69%	(15,365)	-62%	(4,653)	30%
Other, net	(6,369)	-22%	2,366	10%	(8,735)	-369%
Total other expense, net	(26,387)	-91%	(12,999)	-53%	(13,388)	103%
Loss before income taxes	(105,342)	-362%	(82,987)	-336%	(22,355)	27%
Provision for income taxes	(44)	0%	649	3%	(693)	-107%
Net loss	\$ (105,386)	-362%	\$ (82,338)	-333%	\$ (23,048)	28%

### Revenue

Product sales revenue increased by 20% to \$28.7 million for the year ended March 31, 2019, compared with \$23.9 million for the year ended March 31, 2018. The increase in product sales was primarily attributable to growth in product sales to OEM customers and incremental direct sales of conventional reagent products to customers in the United States. Products sold by standing purchase order were 68% of product sales for the year ended March 31, 2019, compared with 75% for the year ended March 31, 2018. Total revenue for the year ended March 31, 2019 increased by 18% to \$29.1 million compared with \$24.7 million in the year ended March 31, 2018, and included other revenues of \$0.5 million and \$0.8 million, respectively.

The below table sets forth revenue by product group:

	Year ended March 31,				Change	
	2019		2018		Amount	%
	Amount	% of revenue	Amount	% of revenue		
	(in thousands, except percentages)					
<b>Revenue:</b>						
Product sales - OEM customers	\$ 20,287	70%	\$ 16,900	68%	\$ 3,387	20%
Product sales - direct customers and distributors	8,378	29%	7,013	28%	1,365	19%
Other revenues	469	2%	819	3%	(350)	-43%
Total revenue	\$ 29,134	100%	\$ 24,732	100%	\$ 4,402	18%

**OEM Sales.** Product sales to OEM customers increased 20% to \$20.3 million for the year ended March 31, 2019, compared with \$16.9 million for the year ended March 31, 2018. The increase was due to increased sales to existing customers and the impact of recently launched new products.

**Direct Sales to Customers and Distributors.** Direct product sales increased 19% to \$8.4 million for the year ended March 31, 2019 compared with \$7.0 million for the year ended March 31, 2018. This mainly consisted of direct sales in the United States which increased to \$7.7 million in the year ended March 31, 2019 compared with \$5.9 million in the year ended March 31, 2018 as a result of recent product launches and the expansion of our customer base.

**Other Revenues.** Other revenues of \$0.5 million for the year ended March 31, 2019 mainly consisted of product development fees. Other revenues of \$0.8 million in the year ended March 31, 2018 consisted of \$0.6 million of product development fees and \$0.2 million of sales of MosaiQ instruments and related products to a development partner. The product development fees in both years arose as the result of the achievement of product development milestones under the terms of our umbrella supply agreement with Ortho. See Note 1 "Summary of Significant Accounting Policies – Revenue Recognition" to our consolidated financial statements included in this Annual Report for additional information. In the year ended March 31, 2018, the cost of the instruments sold to our development partner was included in research and development expenses.

#### Cost of revenue and gross margin

Cost of revenue increased by 65% to \$17.2 million for the year ended March 31, 2019, compared with \$10.5 million for the year ended March 31, 2018. The increase in cost of revenue partially reflected incremental costs associated with greater sales volumes. In addition, in the year ended March 31, 2019, we were in the process of moving our conventional reagents manufacturing operations to the ARC facility, our new facility in Edinburgh, Scotland, the construction of which was completed early in 2018, from our other Edinburgh manufacturing facility. In the year ended March 31, 2019, we incurred additional costs of operating our new ARC facility as well as our previous facility amounting to approximately \$3.8 million, \$1.6 million of which were non-cash expenses, as compared with the single facility that existed in the year ended March 31, 2018. We vacated our previous Edinburgh facility in January 2019.

Gross profit on total revenue in the year ended March 31, 2019 was \$11.9 million, a decrease of 17% when compared with \$14.3 million in the year ended March 31, 2018. This decrease was attributable to the decrease in gross margin on product sales described below and a decrease of \$0.3 million in other revenues to \$0.5 million in the year ended March 31, 2019 as compared with \$0.8 million of other revenues in the year ended March 31, 2018 (the associated cost of which was included in research and development expenses).

Gross profit on product sales, which excludes other revenues, was \$11.4 million for the year ended March 31, 2019 compared with \$13.4 million for the year ended March 31, 2018. This decrease was due to the additional costs of approximately \$3.8 million, \$1.6 million of which were non-cash expenses, of operating two conventional reagent manufacturing facilities in the year ended March 31, 2019 as compared with the single facility that existed in the year ended March 31, 2018, partially offset by the effect of increased sales to existing customers and the impact of recently launched new products. Gross margin on product sales, which excludes other revenues, was 40% for the year ended March 31, 2019 compared with 56% for the year ended March 31, 2018.

#### Sales and marketing expenses

Sales and marketing expense increased by 18% to \$8.6 million for the year ended March 31, 2019, compared with \$7.3 million for the year ended March 31, 2018. The growth in sales and marketing expenses in the year ended March 31, 2019 was mainly attributable to expansion of the MosaiQ commercial team.

#### Research and development expenses

	Year ended March 31,				Change	
	2019		2018		Amount	%
	Amount	% of revenue	Amount	% of revenue		
	(in thousands, except percentages)					
<b>Research and development expenses:</b>						
MosaiQ research and development	\$ 48,903	168%	\$ 50,187	203%	\$ (1,284)	-3%
Other research and development	2,123	7%	1,293	5%	830	64%
Tax credits	(349)	-1%	(278)	-1%	(71)	26%
<b>Total research and development expenses</b>	<b>\$ 50,677</b>	<b>174%</b>	<b>\$ 51,202</b>	<b>207%</b>	<b>\$ (525)</b>	<b>-1%</b>

Research and development expenses decreased by \$0.5 million to \$50.7 million for the year ended March 31, 2019, compared with \$51.2 million for the year ended March 31, 2018. The decrease in costs mainly reflected reduced expenditure with our development partners as the initial development of MosaiQ nears completion. Research and development expenses for the year ended March 31, 2019 included a \$0.5 million expense related to the cost of our intellectual property license with TTP for MosaiQ. There was no equivalent TTP license expense in the year ended March 31, 2018.

**General and administrative expenses**

General and administrative expenses increased 23% to \$31.5 million for the year ended March 31, 2019, compared with \$25.7 million for the year ended March 31, 2018, reflecting greater personnel-related costs as a result of our preparations for the commercialization of MosaiQ, increased advisory fees and costs of \$1.6 million associated with the relocation to our ARC facility. We recognized \$5.0 million of stock compensation expense in the year ended March 31, 2019 compared with \$4.2 million in the year ended March 31, 2018. Stock compensation expense is recognized over the expected vesting period of incentive awards. As a percentage of total revenue, general and administrative expenses increased to 107% for the year ended March 31, 2019, compared with 104% for the year ended March 31, 2018.

**Other income (expense)**

Net interest expense was \$20.0 million for the year ended March 31, 2019, compared with \$15.4 million for the year ended March 31, 2018. Interest expense in the year ended March 31, 2019 included \$13.3 million of interest charges on our Secured Notes compared with \$10.1 million in the year ended March 31, 2018. The increase was due to the additional issuance of \$36 million of Secured Notes on June 29, 2018. Interest expense in the years ended March 31, 2019 and March 31, 2018 included amortization of deferred debt issue costs of \$5.9 million and \$4.4 million, respectively, which included, in the year ended March 31, 2019, amortization of the expected costs of the royalty rights agreements entered into in October 2016, June 2018 and December 2018 in connection with the issuances of the Secured Notes and the amendment of the indenture relating to the Secured Notes and, in the year ended March 31, 2018, amortization of the expected costs of the royalty rights agreements entered into in October 2016 in connection with the issuance of the Secured Notes. In each of the years ended March 31, 2019 and March 31, 2018, net interest expense also included \$1.1 million of accrued dividends on the 7% cumulative redeemable preference shares issued in January 2015. In addition, in the year ended March 31, 2019 we earned interest income of \$0.3 million on our money market deposits as compared with \$0.2 million in the year ended March 31, 2018.

Other expense for the year ended March 31, 2019 included \$5.4 million of foreign exchange losses arising on monetary assets and liabilities denominated in foreign currencies and \$1.0 million of fees related to the amendment of the indenture relating to the Secured Notes in December 2018. Other income for the year ended March 31, 2018 included \$2.4 million of foreign exchange gains arising on monetary assets and liabilities denominated in foreign currencies.

**Provision for income taxes**

Provision for income taxes in the year ended March 31, 2019 reflected a reduction in the net operating losses available to be carried forward in a subsidiary as a result of the offset of historic tax losses against the profits of this subsidiary. Provision for income taxes in the year ended March 31, 2018 reflected a reduction in the valuation allowance against deferred tax assets in a subsidiary as a result of an improvement in the profitability of this subsidiary.

### Comparison of Years ended March 31, 2018 and 2017

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

	Year ended March 31,					
	2018		2017		Change	
	Amount	% of revenue	Amount	% of revenue	Amount	%
(in thousands, except percentages)						
<b>Revenue:</b>						
Product sales	\$ 23,913	97%	\$ 20,127	91%	\$ 3,786	19%
Other revenues	819	3%	2,100	9%	(1,281)	-61%
Total revenue	24,732	100%	22,227	100%	2,505	11%
Cost of revenue	10,471	42%	10,844	49%	(373)	-3%
Gross profit	14,261	58%	11,383	51%	2,878	25%
<b>Operating expenses:</b>						
Sales and marketing	7,347	30%	5,660	25%	1,687	30%
Research and development	51,202	207%	57,064	257%	(5,862)	-10%
General and administrative	25,700	104%	22,718	102%	2,982	13%
Total operating expenses	84,249	341%	85,442	384%	(1,193)	-1%
Operating (loss)	(69,988)	-283%	(74,059)	-333%	4,071	-5%
<b>Other income (expense):</b>						
Interest expense, net	(15,365)	-62%	(9,903)	-45%	(5,462)	55%
Other, net	2,366	10%	(1,107)	-5%	3,473	-314%
Total other expense, net	(12,999)	-53%	(11,010)	-50%	(1,989)	18%
Loss before income taxes	(82,987)	-336%	(85,069)	-383%	2,082	-2%
Provision for income taxes	649	3%	—	—	649	100%
Net loss	\$ (82,338)	-333%	\$ (85,069)	-383%	\$ 2,731	-3%

### Revenue

Product sales revenue increased by 19% to \$23.9 million for the year ended March 31, 2018, compared with \$20.1 million for the year ended March 31, 2017. The increase in product sales was primarily attributable to growth in product sales to OEM customers and incremental direct sales of conventional reagent products to customers in the United States. Products sold by standing purchase order were 75% of product sales for the year ended March 31, 2018, compared with 76% for the year ended March 31, 2017. Total revenue for the years ended March 31, 2018 and 2017 also included other revenues of \$0.8 million and \$2.1 million, respectively. Total revenue increased by 11% to \$24.7 million for the year ended March 31, 2018, compared with \$22.2 million for the year ended March 31, 2017.

The below table sets forth revenue by product group:

	Year ended March 31,					
	2018		2017		Change	
	Amount	% of revenue	Amount	% of revenue	Amount	%
(in thousands, except percentages)						
<b>Revenue:</b>						
Product sales - OEM customers	\$ 16,900	68%	\$ 14,216	64%	\$ 2,684	19%
Product sales - direct customers and distributors	7,013	28%	5,911	27%	1,102	19%
Other revenues	819	3%	2,100	9%	(1,281)	-61%
Total revenue	\$ 24,732	100%	\$ 22,227	100%	\$ 2,505	11%

**OEM Sales.** Product sales to OEM customers increased 19% to \$16.9 million for the year ended March 31, 2018, compared with \$14.2 million for the year ended March 31, 2017. The increase was due to increased sales to existing customers and the impact of recently launched new products.

**Direct Sales to Customers and Distributors.** Direct product sales increased 19% to \$7.0 million for the year ended March 31, 2018 compared with \$5.9 million for the year ended March 31, 2017. This mainly consisted of direct sales in the United States which increased to \$5.9 million in the year ended March 31, 2018 compared with \$5.5 million in the year ended March 31, 2017 as a result of recent product launches, the expansion of our customer base and improved revenue hedging arrangements in the year ended March 31, 2018 as compared with the year ended March 31, 2017.

**Other Revenues.** Other revenues of \$0.8 million for the year ended March 31, 2018 consisted of \$0.6 million of product development fees and \$0.2 million of sales of MosaiQ instruments and related products to a development partner. Other revenues of \$2.1 million in the year ended March 31, 2017, consisted entirely of product development fees. The product development fees in both years arose as the result of the achievement of product development milestones under the terms of our umbrella supply agreement with Ortho. See Note 1 "Summary of Significant Accounting Policies – Revenue Recognition" to our consolidated financial statements included in this Annual Report for additional information. The cost of the instruments sold to our development partner was included in research and development expenses.

#### Cost of revenue and gross margin

Cost of revenue decreased by 3% to \$10.5 million for the year ended March 31, 2018, compared with \$10.8 million for the year ended March 31, 2017. The decrease in cost of revenue reflected improved product mix and efficiencies in our manufacturing operations, which were offset in part by incremental costs associated with greater sales volumes.

Gross profit on total revenue in the year ended March 31, 2018 was \$14.3 million, an increase of 25% when compared with \$11.4 million in the year ended March 31, 2017. This increase was attributable to the increase in gross margin on product sales described below offset in part by a reduction of \$1.3 million of other revenues in the year ended March 31, 2017 (the associated cost of which was included in research and development expenses).

Gross margin, which represents gross profit expressed as a percentage of total revenue, was 58% for the year ended March 31, 2018, compared with 51% for the year ended March 31, 2017. Gross margin on product sales, which excludes other revenues, was 56% for the year ended March 31, 2018, compared with 46% for the year ended March 31, 2017 due to the positive impact of our revenue hedging arrangements, improved product and customer mix and efficiencies at our then-existing manufacturing facility in Edinburgh, Scotland in the year ended March 31, 2018 compared with the year ended March 31, 2017.

#### Sales and marketing expenses

Sales and marketing expense increased by 30% to \$7.3 million for the year ended March 31, 2018, compared with \$5.7 million for the year ended March 31, 2017. The growth in sales and marketing expenses in the year ended March 31, 2018 was mainly attributable to the MosaiQ commercial team.

#### Research and development expenses

	Year ended March 31,				Change	
	2018		2017		Amount	%
	Amount	% of revenue	Amount	% of revenue		
	(in thousands, except percentages)					
<b>Research and development expenses:</b>						
MosaiQ research and development	\$ 50,187	203%	\$ 55,610	250%	\$ (5,423)	-10%
Other research and development	1,293	5%	1,858	8%	(565)	-30%
Tax credits	(278)	-1%	(404)	-2%	126	-31%
Total research and development expenses	<u>\$ 51,202</u>	<u>207%</u>	<u>\$ 57,064</u>	<u>257%</u>	<u>\$ (5,862)</u>	<u>-10%</u>

Research and development expenses decreased by \$5.9 million to \$51.2 million for the year ended March 31, 2018, compared with \$57.1 million for the year ended March 31, 2017. The decrease in costs mainly reflected reduced expenditure with our development partners as the initial development of MosaiQ nears completion. In addition, research and development expenses for the year ended March 31, 2017 included a \$2.0 million expense related to the cost of our intellectual property license with TTP for MosaiQ. There was no equivalent TTP license expense in the year ended March 31, 2018.

**General and administrative expenses**

General and administrative expenses increased 13% to \$25.7 million for the year ended March 31, 2018, compared with \$22.7 million for the year ended March 31, 2017. We recognized \$4.2 million of stock compensation expense in the year ended March 31, 2018 compared with \$4.2 million in the year ended March 31, 2017. Stock compensation expense is recognized over the expected vesting period of incentive awards. In the year ended March 31, 2018, there were greater personnel-related costs as a result of our preparations for the commercialization of MosaiQ and our relocation to the ARC facility. As a percentage of total revenue, general and administrative expenses increased to 104% for the year ended March 31, 2018, compared with 102% for the year ended March 31, 2017.

**Other income (expense)**

Net interest expense was \$15.4 million for the year ended March 31, 2018, compared with \$9.9 million for the year ended March 31, 2017. Interest expense in the year ended March 31, 2018 included \$10.1 million of interest charges on our Secured Notes. Interest expense in the year ended March 31, 2017 included \$4.6 million of interest charges on the Secured Notes for the period from October 14, 2016 to March 31, 2017 and \$1.4 million of interest charges on our borrowings under our former secured term loan facility with MidCap Financial Trust (or MidCap) from April 1, 2016 to October 14, 2016. Borrowings from Midcap amounted to \$30.0 million from April 1, 2016 to October 14, 2016, bore interest at LIBOR plus 6.7% (with a LIBOR floor of 2.00%) and were repaid from the proceeds of the issue of the Secured Notes. Interest expense in the years ended March 31, 2018 and March 31, 2017 included amortization of deferred debt issue costs of \$4.4 million and \$2.7 million, respectively which included amortization of the expected costs of the royalty rights agreements entered into in October 2016 in connection with the issuance of the Secured Notes. In each of the years ended March 31, 2018 and March 31, 2017, net interest expense also included \$1.1 million of accrued dividends on the 7% cumulative redeemable preference shares issued in January 2015. In addition, in the year ended March 31, 2018 we earned interest income of \$0.2 million on our money market deposits.

Other income for the year ended March 31, 2018 included \$2.4 million of foreign exchange gains arising on monetary assets and liabilities denominated in foreign currencies. Other expense for the year ended March 31, 2017 included \$4.0 million of deferred debt costs related to our borrowings from MidCap, which were expensed on repayment of the MidCap borrowings, offset by \$2.9 million of foreign exchange gains arising on monetary assets and liabilities denominated in foreign currencies.

**Provision for income taxes**

Provision for income taxes in the year ended March 31, 2018 reflected a reduction in the valuation allowance against deferred tax assets in a subsidiary as a result of an improvement in the profitability of this subsidiary. No provision for income taxes arose in the year ended March 31, 2017.

## Quarterly Results of Operations

The following table sets forth selected unaudited consolidated quarterly statements of operations data for our eight most recent completed fiscal quarters. We have prepared the consolidated quarterly operations data on a basis consistent with the audited consolidated financial statements included elsewhere in this Annual Report. In the opinion of management, the quarterly consolidated operations data reflects all necessary adjustments, consisting only of normal recurring adjustments, necessary for a fair presentation of this data. Historical results are not necessarily indicative of the results to be expected in future periods and the results for a quarterly period are not necessarily indicative of the operating results for a full year. This information should be read in conjunction with the consolidated financial statements included elsewhere in this Annual Report.

	2019		2018			2017		
	Mar 31	Dec-31	Sep-30	Jun-30	Mar 31	Dec 31	Sept 30	June 30
	(in thousands, except percentages)							
<b>Revenue:</b>								
Product sales	\$ 7,831	\$ 6,723	\$ 6,247	\$ 7,864	\$ 6,124	\$ 5,653	\$ 5,910	\$ 6,226
Other revenues	450	—	—	19	13	206	—	600
Total revenue	8,281	6,723	6,247	7,883	6,137	5,859	5,910	6,826
Cost of revenue	(4,427)	(4,186)	(4,552)	(4,065)	(2,528)	(2,325)	(2,786)	(2,832)
Gross profit	3,854	2,537	1,695	3,818	3,609	3,534	3,124	3,994
<b>Operating expenses:</b>								
Sales and marketing	(2,278)	(2,233)	(1,845)	(2,281)	(1,886)	(1,910)	(1,869)	(1,682)
Research and development	(13,321)	(11,788)	(12,998)	(12,570)	(13,259)	(11,929)	(13,341)	(12,673)
General and administrative	(8,580)	(7,544)	(7,916)	(7,505)	(6,391)	(6,790)	(5,974)	(6,545)
Total operating expenses	(24,179)	(21,565)	(22,759)	(22,356)	(21,536)	(20,629)	(21,184)	(20,900)
Operating profit (loss)	(20,325)	(19,028)	(21,064)	(18,538)	(17,927)	(17,095)	(18,060)	(16,906)
<b>Other income (expense):</b>								
Interest expense, net	(5,404)	(5,679)	(5,819)	(3,116)	(3,709)	(3,249)	(4,197)	(4,210)
Other, net	(853)	(1,536)	(468)	(3,512)	888	33	565	880
Total other income (expense), net	(6,257)	(7,215)	(6,287)	(6,628)	(2,821)	(3,216)	(3,632)	(3,330)
Loss before income taxes	(26,582)	(26,243)	(27,351)	(25,166)	(20,748)	(20,311)	(21,692)	(20,236)
Provision for income taxes	(11)	(11)	(11)	(11)	649	—	—	—
Net loss	\$ (26,593)	\$ (26,254)	\$ (27,362)	\$ (25,177)	\$ (20,099)	\$ (20,311)	\$ (21,692)	\$ (20,236)
% of Product Sales from Standing Purchase Orders	70%	67%	70%	65%	77%	76%	68%	79%

Our quarterly product sales can fluctuate depending upon the shipment cycles for our red blood cell-based products, which account for approximately two-thirds of our current product sales. For these products, we typically experience 13 shipping cycles per year. This equates to three shipments of each product per quarter, except for one quarter per year when four shipments occur. In fiscal 2019 and in fiscal 2018, the greatest impact of extra product shipments occurred in our first quarter. The timing of shipment of bulk antisera products to our OEM customers may also move revenues from quarter to quarter. We also experience some seasonality in demand around holiday periods in both Europe and the United States. As a result of these factors, we expect to continue to see seasonality and quarter-to-quarter variations in our product sales.

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

## Liquidity and Capital Resources

Since our commencement of operations in 2007, we have incurred net losses and negative cash flows from operations. As of March 31, 2019, we had an accumulated deficit of \$381.0 million. During the year ended March 31, 2019, we incurred a net loss of \$105.4 million and used \$75.7 million of cash for operating activities. During the year ended March 31, 2018, we incurred a net loss of \$82.3 million and used \$68.4 million of cash for operating activities. During the year ended March 31, 2017, we incurred a net loss of \$85.1 million and used \$56.2 million of cash for operating activities. As described under results of operations, our use of cash during the years ended March 31, 2019 and March 31, 2018 was primarily attributable to our investment in the development of MosaiQ, the construction of the ARC facility near Edinburgh, Scotland and corporate costs, including costs related to being a public company.

From our incorporation in 2012 to March 31, 2018, we have raised \$110.8 million of gross proceeds through the private placement of our ordinary and preference shares and warrants, \$181.1 million of gross proceeds from public offerings of our shares and issuances of ordinary shares upon exercise of warrants and \$84.0 million of gross proceeds from the issuance of the Secured Notes.

On June 29, 2018, we issued an additional \$36.0 million aggregate principal amount of the Secured Notes. As referenced above, we previously issued \$84.0 million aggregate principal amount of the Secured Notes on October 14, 2016. On June 29, 2018, we paid \$2.2 million of the net proceeds of the issuance of the additional Secured Notes into the cash reserve account maintained with the collateral agent under the terms of the indenture governing the Secured Notes, which together with the \$5.0 million paid into the cash reserve account on October 14, 2016, brought the total in the cash reserve account to \$7.2 million at March 31, 2019.

In the period between March 31, 2018 and July 31, 2018, 8,414,683 warrants that were previously issued in connection with our October 2017 private placement of ordinary shares were exercised for 8,414,683 ordinary shares at \$5.80 per share, which generated \$48.8 million of proceeds.

On August 3, 2018, we entered into two subscription agreements with Franz Walt, our Chief Executive Officer, and with Heino von Prondzynski, our Chairman, pursuant to which we issued a combined total of 55,000 ordinary shares at a price of \$7.54 per share (which was equal to the closing bid price of our ordinary shares as reported on the Nasdaq Global Market on August 2, 2018) for aggregate proceeds of \$0.4 million.

On December 11, 2018, we completed a public offering of 10,615,385 newly issued ordinary shares at a price of \$6.50 per share which raised \$69 million of gross proceeds before underwriting discounts and other offering expenses.

On December 18, 2018, we completed certain amendments to the indenture governing the Secured Notes. These amendments included a six-month extension of the final maturity of the Secured Notes to April 2024 and a revision of the Secured Notes' principal amortization (previously scheduled to commence semi-annually beginning April 2019) to commence April 2021, in order to better align the maturity and amortization schedule with our financial goals. The revised amortization schedule defers approximately \$39.6 million of principal amortization previously scheduled to occur between April 2019 and April 2021. In addition, the amendments include a one-year extension of the optional redemption call schedule to October 2022. In consideration for the consents to the amendments, we paid to the noteholders a one-time consent payment of \$3.9 million and we issued additional royalty rights to the noteholders, which increased in the aggregate the amount of the royalties payable under the royalty rights that were previously issued by us in connection with the prior issuances of the Secured Notes by 1%, from 2% to 3%, of the aggregate net sales of MosaiQ instruments and consumables in specified markets.

The amendments also increased the aggregate principal amount of Secured Notes that can be issued under the indenture from \$120 million to up to \$145 million following the European CE Marking of our initial MosaiQ IH Microarray. On January 15, 2019, we entered into purchase agreements pursuant to which we agreed to issue and certain purchasers agreed to purchase the additional \$25 million of the Secured Notes. On May 1, 2019, we announced that the CE Mark of our initial MosaiQ Microarray had been granted, and, on May 15, 2019, we issued an additional \$25 million of the Secured Notes. We also issued royalty rights to the purchasers representing the right to receive 0.4% of the aggregate net sales of MosaiQ instruments and consumable in specified markets.

As of March 31, 2019, we had available cash, cash equivalents and short-term investments of \$94.8 million and \$7.5 million of restricted cash held as part of the arrangements relating to our Secured Notes and the lease of our property in Eysins, Switzerland.

#### **12% Senior Secured Notes Due 2024**

As described above, on October 14, 2016, we completed a private placement of our Secured Notes. Our obligations under the Secured Notes and the related indenture are unconditionally guaranteed on a secured basis by the guarantors, which include all our subsidiaries, and the indenture contains customary events of default. We must also comply with certain customary affirmative and negative covenants, including a requirement to maintain six-months of interest in a cash reserve account maintained with the collateral agent.

We issued \$84 million aggregate principal amount of the Secured Notes on October 14, 2016, an additional \$36 million aggregate principal amount of the Secured Notes on June 29, 2018 and an additional \$25 million of the Secured Notes on May 15, 2019.



Upon the occurrence of a Change of Control, subject to certain conditions, or certain Asset Sales (each, as defined in the indenture), holders of the Secured Notes may require us to repurchase for cash all or part of their Secured Notes at a repurchase price equal to 101% or 100%, respectively, of the principal amount of the Secured Notes to be repurchased, plus accrued and unpaid interest to the date of repurchase.

We paid \$7.2 million of the total proceeds of the October 2016 and June 2018 issuances into the cash reserve account maintained with the collateral agent under the terms of the indenture, \$2.2 million of which related to the second issuance. We paid a further \$1.5 million into the cash reserve account on May 15, 2019 in connection with the issuance of the additional \$25 million of Secured Notes on that date.

Interest on the Secured Notes accrues at a rate of 12% per annum and is payable semi-annually on April 15 and October 15 of each year commencing on April 15, 2017. Commencing on April 15, 2021, we will also pay an installment of principal of the Secured Notes on each April 15 and October 15 until April 15, 2024 pursuant to a fixed amortization schedule.

In connection with the October 2016 and June 2018 issuances of the Secured Notes as well as the December 2018 amendment of the related indenture, we entered into royalty rights agreements, pursuant to which we agreed to pay 3.0% of the aggregate net sales of MosaiQ instruments and consumables made in the donor testing market in the United States and the European Union. Further, pursuant to the issuance of the additional \$25 million of Secured Notes on May 15, 2019, we also entered into royalty rights agreements pursuant to which we agreed to pay an additional 0.4% of such net sales. The royalties will be payable beginning on the date that we make our first sale of MosaiQ consumables in the donor testing market in the European Union or the United States and will end on the last day of the calendar quarter in which the eighth anniversary of the first sale date occurs.

Using the proceeds of the Secured Notes issued in October 2016, we repaid in full on that day our borrowings under our previous secured term loan facility with MidCap, which amounted to \$33.5 million including fees and expenses.

#### **Cash Flows for the Years Ended March 31, 2019 and 2018**

##### **Operating activities**

Net cash used in operating activities was \$75.7 million during the year ended March 31, 2019, which included net losses of \$105.4 million and non-cash items of \$25.7 million. Non-cash items were depreciation and amortization expense of \$12.8 million, share-based compensation expense of \$5.0 million, amortization of lease incentives of \$0.4 million, Swiss pension costs of \$0.6 million, amortization of deferred debt issue costs of \$5.9 million and accrued preference share dividends of \$1.0 million. We also experienced a net cash inflow of \$4.1 million from changes in operating assets and liabilities during the period, consisting of a \$3.3 million decrease in other assets, a \$0.4 million increase in accounts payable and accrued liabilities and a \$1.1 million increase in accrued compensation and benefits offset by a \$0.1 million increase in inventories and a \$0.6 million increase in accounts receivable.

Net cash used in operating activities was \$68.4 million during the year ended March 31, 2018, which included net losses of \$82.3 million and non-cash items of \$19.5 million. Non-cash items were depreciation and amortization expense of \$10.4 million, share-based compensation expense of \$4.2 million, Swiss pension costs of \$0.7 million, amortization of deferred debt issue costs of \$4.4 million and accrued preference share dividends of \$1.0 million, offset by deferred income taxes of \$0.6 million and amortization of lease incentives of \$0.4 million. We also experienced a net cash outflow of \$5.6 million from changes in operating assets and liabilities during the period, consisting of a \$3.3 million reduction in accounts payable and accrued liabilities, a \$1.7 million increase in inventories, a \$0.1 million increase in accounts receivable and a \$2.1 million increase in other assets offset by a \$1.6 million increase in accrued compensation and benefits.

##### **Investing activities**

Net cash used in investing activities was \$89.1 million in the year ended March 31, 2019 and net cash from investing activities was \$3.3 million in the year ended March 31, 2018. We invested \$84.3 million net in a short-term money market fund in the year ended March 31, 2019 and withdrew \$10.4 million net in the year ended March 31, 2018. Purchases of property and equipment in the years ended March 31, 2019 and March 31, 2018 were \$4.8 million and \$21.6 million, respectively. Most of these expenditures related to the construction of the ARC facility and we generated \$14.7 million, net of a rent deposit payment in the year ended March 31, 2018 from the sale and leaseback of this building. We also invested \$0.2 million in the year March 31, 2018 on new product licenses within our conventional reagent operations.

**Financing activities**

Net cash provided by financing activities was \$145.4 million during the year ended March 31, 2019, consisting of \$34.8 million of net proceeds from the issuance of additional Secured Notes on June 29, 2018, payment of \$3.9 million of consent fees in December 2018 related to the amendment of the indenture governing the Secured Notes and \$115.0 million of proceeds from the issuance of ordinary shares (including \$50.1 million in connection with the exercise of warrants and share options), offset by \$0.5 million of repayments on finance leases.

Net cash provided by financing activities was \$83.3 million (including our April 2017 public offering of ordinary shares and our October 2017 private placement of ordinary shares and warrants) during the year ended March 31, 2018, consisting of \$85.0 million of net proceeds from the issuance of ordinary shares and warrants and exercise of share options offset by \$1.7 million of repayments on finance leases.

**Cash Flows for the Years Ended March 31, 2018 and 2017****Operating activities**

Net cash used in operating activities was \$68.4 million during the year ended March 31, 2018, which included net losses of \$82.3 million and non-cash items of \$19.5 million. Non-cash items were depreciation and amortization expense of \$10.4 million, share-based compensation expense of \$4.2 million, Swiss pension costs of \$0.7 million, amortization of deferred debt issue costs of \$4.4 million and accrued preference share dividends of \$1.0 million, offset by deferred income taxes of \$0.6 million and amortization of lease incentives of \$0.4 million. We also experienced a net cash outflow of \$5.6 million from changes in operating assets and liabilities during the period, consisting of a \$3.3 million reduction in accounts payable and accrued liabilities, a \$1.7 million increase in inventories, a \$0.1 million increase in accounts receivable and a \$2.1 million increase in other assets offset by a \$1.6 million increase in accrued compensation and benefits.

Net cash used in operating activities was \$56.2 million during the year ended March 31, 2017, which included net losses of \$85.1 million and non-cash items of \$21.7 million. Non-cash items were depreciation and amortization expense of \$9.5 million, share-based compensation expense of \$4.2 million, Swiss pension costs of \$0.6 million, amortization of deferred debt issue costs of \$6.8 million and accrued preference share dividends of \$1.1 million, offset by amortization of lease incentives of \$0.4 million. We also experienced a net cash inflow of \$7.2 million from changes in operating assets and liabilities during the period, consisting primarily a \$10.0 million increase in accounts payable and accrued liabilities and a \$0.8 million increase in accrued compensation and benefits offset by a \$1.8 million increase in inventories, a \$0.6 million increase in accounts receivable and a \$1.2 million increase in other assets.

**Investing activities**

Net cash from investing activities was \$3.3 million in the year ended March 31, 2018 and net cash used in investing activities was \$36.3 million in the year ended March 31, 2017. We invested \$16.0 million (net) in a short-term money market fund in the year ended March 31, 2017 and withdrew \$10.4 million (net) in the year ended March 31, 2018. Purchases of property and equipment in the years ended March 31, 2018 and March 31, 2017 were \$21.6 million and \$20.2 million, respectively. Most of these expenditures related to the construction of the ARC facility and we generated \$14.7 million, net of a rent deposit payment in the year ended March 31, 2018 from the sale and leaseback of this building. We also invested \$0.2 million and \$0.1 million in the years ended March 31, 2018 and March 31, 2017, respectively, on new product licenses within our conventional reagent operations.

**Financing activities**

Net cash provided by financing activities was \$83.3 million (including our April 2017 public offering of ordinary shares and our October 2017 private placement of ordinary shares and warrants) during the year ended March 31, 2018, consisting of \$85.0 million of net proceeds from the issuance of ordinary shares and warrants and exercise of share options offset by \$1.7 million of repayments on finance leases.

Net cash provided by financing activities was \$56.5 million during the year ended March 31, 2017, consisting primarily of net proceeds of \$16.4 million from our August 2016 public offering of ordinary shares, \$0.3 million from the issue of other ordinary shares and \$45.0 million of proceeds from new debt net of issue costs and repayment of our previous MidCap facility, offset by \$5.0 million paid into a cash reserve account maintained with the collateral agent for the Secured Notes and \$0.1 million of repayments on finance leases.

## Operating and Capital Expenditure Requirements

We have not achieved profitability on an annual basis since we commenced operations in 2007 and we expect to incur net losses for at least the next fiscal year. As we move towards the commercial launch of MosaiQ, we expect our operating expenses during the year ended March 31, 2020 to be similar to those of the year ended March 31, 2019, as we continue to invest in growing our customer base, expanding our marketing and distribution channels, hiring additional employees and investing in other product development opportunities while development expenditure on MosaiQ reduces.

As of March 31, 2019, we had available cash, cash equivalents and short-term investments of \$94.8 million and \$7.5 million of restricted cash held as part of the arrangements relating to our Secured Notes and the lease of our property in Eysins, Switzerland.

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

- our progress in developing and commercializing MosaiQ and the cost required to complete development, obtain regulatory approvals and complete our manufacturing scale up;
- Ortho's progress in commercializing MosaiQ for the patient testing market;
- our ability to manufacture and sell our conventional reagent products, including the costs and timing of further expansion of our sales and marketing efforts;
- our ability to collect our accounts receivable;
- our ability to generate cash from operations;
- any acquisition of businesses or technologies that we may undertake; and
- our ability to penetrate our existing market and new markets.

We expect to fund our operations, including the ongoing development of MosaiQ through successful field trial completion, achievement of required regulatory authorizations and commercialization from the use of existing available cash and short-term investment balances and the issuance of new equity or debt. Our existing available cash and short-term investment balances are adequate to meet our forecasted cash requirements for the next twelve months and accordingly we have prepared the financial statements on the going concern basis.

## Contractual Obligations

We have contractual obligations for non-cancelable facilities leases, our Secured Notes and related royalty rights agreements, equipment leases and purchase commitments. The following table sets forth a summary of our contractual obligations as of March 31, 2019.

Contractual Obligations	Payment by period				
	Total	Less than 1 year	1 to 3 years	3 to 5 years	After 5 years
12% Senior Secured Notes due 2023	\$ 120,000	\$ —	\$ 20,000	\$ 75,000	\$ 25,000
Interest on 12% Senior Secured Notes	61,800	14,400	28,200	17,700	1,500
Royalty rights agreements with note purchasers	74,447	—	2,325	14,731	57,391
7% Cumulative Redeemable Preference Shares (1)	15,000	—	15,000	—	—
Dividends on 7% Cumulative Redeemable Preference Shares (1)	6,300	—	6,300	—	—
Operating and capital leases	83,620	3,858	4,394	3,861	71,507
STRATEC Biomedical manufacturing agreement (2)	65,043	1,153	14,408	31,122	18,360
Other	14,131	13,482	649	—	—
Total contractual obligations	\$ 440,341	\$ 32,893	\$ 91,276	\$ 142,414	\$ 173,758

- (1) The 7% Cumulative Redeemable Preference Shares are redeemable at the option of the shareholders on a date not before January 29, 2021, which can be extended at our option in one year increments until January 29, 2025. We can pay dividends on the 7% Cumulative Redeemable Preference Shares at any time, but are not obligated to do so until redemption.
- (2) We have entered into a manufacturing agreement with STRATEC in connection with the supply of MosaiQ instruments over a six year period. The total purchase obligation under this agreement is \$65.0 million (€58.0 million) using March 31, 2019 exchange rates.

On May 15, 2019, we issued an additional \$25 million aggregate principal amount of the Secured Notes and entered into additional royalty rights agreements with the purchasers of the Secured Notes. The table above does not reflect the obligations under such additional Secured Notes and additional royalty rights agreements.

#### **Critical Accounting Policies and Significant Judgments and Estimates**

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

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

#### **Revenue recognition and accounts receivable**

Revenue is recognized in accordance with Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*. Product revenue is recognized at a point in time upon transfer of control of a product to a customer, which is generally at the time of delivery at an amount based on the transaction price. Customers have no right of return except in the case of damaged goods and the Company has not experienced any significant returns of its products.

We also earn revenue from the provision of development services to a small number of OEM customers. These development service contracts are reviewed individually to determine the nature of the performance obligations and the associated transaction prices. In recent years, our product development revenues have been commensurate with achieving milestones specified in the respective development agreements relating to those products. These milestones may include the approval of new products by the European or U.S. regulatory authorities, which are not within our control. While there can be no assurance that this will continue to be the case, the nature of the milestones has been such that they effectively represent completion of our performance obligations under a particular part of a development program. Should we fail to achieve these milestones we are not entitled under the terms of the development agreements to any compensation related to the work undertaken to date. As a result, we typically fully recognize milestone-related revenues as the contractual milestones are achieved.

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

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

#### **Inventories**

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

#### **Income taxes**

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

We follow the accounting guidance for uncertainties in income taxes, which prescribes a recognition threshold and measurement process for recording uncertain tax positions taken, or expected to be taken, in a tax return in the financial statements. Additionally, the guidance also prescribes the derecognition, classification, accounting in interim periods and disclosure requirements for uncertain tax positions. We accrue for the estimated amount of taxes for uncertain tax positions if it is more likely than not that we would be required to pay such additional taxes. An uncertain tax position will not be recognized if it has less than a 50% likelihood of being sustained. We did not have any accrued interest or penalties associated with any unrecognized tax positions, and there were no such interest or penalties recognized during the years ended March 31, 2019, 2018 or 2017.

#### **Stock compensation expense**

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

#### **Defined benefit pension obligations**

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

**Royalty liability**

The royalty rights agreements entered into in connection with the issue of the Secured Notes are treated as sales of future revenues that meet the requirements of ASC Topic 470 "Debt" to be treated as debt. The estimated future cash outflows under the royalty rights agreements have been combined with the issuance costs and interest payable to calculate the effective interest rate of the Secured Notes and will be expensed through interest expenses using the effective interest rate method over the term of the Secured Notes and royalty rights agreements. Estimating the future cash outflows under the royalty rights agreements requires us to make certain estimates and assumptions about future sales of MosaiQ products. These estimates of the magnitude and timing of MosaiQ sales are subject to significant variability due to the current status of development of MosaiQ products, and thus are subject to significant uncertainty. Therefore, the estimates are likely to change as we gain experience of marketing MosaiQ, which may result in future adjustments to the accretion of the interest expense and the amortized cost based carrying value of the Secured Notes.

**Off-Balance Sheet Arrangements**

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

**Recent Accounting Pronouncements**

Refer to Note 1 to our accompanying audited financial statements included elsewhere in this report for a discussion of recently issued accounting pronouncements.

**JOBS Act**

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

#### **Item 7A. Quantitative and Qualitative Disclosures About Market Risk**

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

##### **Interest rate sensitivity**

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

**Cash, cash equivalents and cash reserve account.** At March 31, 2019, we had cash and cash equivalents of \$94.8 million and we also held \$7.5 million of restricted cash. Our exposure to market risk includes interest income sensitivity, which is impacted by changes in the general level of U.S. and European interest rates. Our cash and cash equivalents and the cash reserve account are held in interest-bearing savings accounts and bank accounts. We do not enter into investments for trading or speculative purposes. Due to the current levels of interest rates, we do not believe an immediate one percentage point change in interest rates would have a material effect on the fair market value of our holdings, and therefore we do not expect our operating results or cash flows to be significantly affected by changes in market interest rates.

**Senior Secured Notes.** At March 31, 2019, we had term debt of \$120.0 million outstanding under the Secured Notes. The Secured Notes are fixed-rate instruments and, as a result, a change in market interest rates has no impact on our interest expense incurred or cash flows.

##### **Foreign currency exchange risk**

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

We are subject to market risks arising from changes in foreign currency exchange rates between the U.S. Dollar and the Pound Sterling and the U.S. Dollar and the Swiss Franc. Accordingly, fluctuations in the U.S. Dollar versus Pounds Sterling and the U.S. Dollar versus the Swiss Franc exchange rate give rise to exchange gains and losses. These gains and losses arise from the conversion of U.S. Dollars and Euros to Pounds Sterling and the retranslation of cash, accounts receivable, intercompany indebtedness and other asset and liability balances. Based on our assets and liabilities held in Pounds Sterling at March 31, 2019, we estimate that a 5% strengthening of the Pound Sterling against the U.S. Dollar would give rise to a gain of approximately \$0.8 million and a 5% weakening of the Pound Sterling against the U.S. Dollar would give rise to loss of approximately \$0.8 million. Based on our assets and liabilities held in Swiss Francs at March 31, 2019, we estimate that a 5% strengthening of the Swiss Franc against the U.S. Dollar would give rise to a gain of approximately \$1.2 million and a 5% weakening of the Swiss Franc against the U.S. Dollar would give rise to loss of approximately \$1.2 million.

Most of our revenues are earned in U.S. Dollars, but the costs of our conventional reagent manufacturing operations are payable mainly in Pounds Sterling. We therefore closely monitor the results of our UK operations to address this difference. During the year ended March 31, 2019, the net operating expenses arising in Pounds Sterling from our UK conventional reagent manufacturing operations amounted to approximately \$27.0 million. This expenditure is offset by revenues arising in U.S. Dollars and other currencies. We have entered into forward contracts to hedge against the effects of fluctuations in the U.S. Dollar versus the Pounds Sterling exchange rate. The principal value of the hedges related to the results of fiscal year 2020 is \$4.5 million and, based on this, a hypothetical instantaneous 5% strengthening of the Pound Sterling against the U.S. Dollar would reduce our net income by \$1.1 million in the year ending March 31, 2020 after taking account of the shelter provided by our existing hedging arrangements through March 31, 2020. Similarly, a hypothetical instantaneous 5% weakening of the Pound Sterling against the U.S. Dollar would increase group net income by \$1.1 million over the same period.

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

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

**Item 8. Financial Statements and Supplementary Data**

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



---

Index to financial statements

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

---

	Page
<a href="#">Report of Independent Registered Public Accounting Firm</a>	64
<a href="#">Consolidated Balance Sheets as of March 31, 2019 and 2018</a>	65
<a href="#">Consolidated Statements of Comprehensive Loss for the years ended March 31, 2019, 2018 and 2017</a>	66
<a href="#">Consolidated Statements of Changes in Shareholders' Equity (Deficit) for the years ended March 31, 2019, 2018 and 2017</a>	67
<a href="#">Consolidated Statements of Cash Flows for the years ended March 31, 2019, 2018 and 2017</a>	68
<a href="#">Notes to Consolidated Financial Statements</a>	69

---

**Report of Independent Registered Public Accounting Firm**  
**To the Shareholders and the Board of Directors of Quotient Limited**  
**Opinion on the Financial Statements**

We have audited the accompanying consolidated balance sheets of Quotient Limited (the Company) as of March 31, 2019 and 2018, the related consolidated statements of comprehensive loss, shareholders' equity (deficit) and cash flows for each of the three years in the period ended March 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at March 31, 2019 and 2018, and the results of its operations and its cash flows for each of the three years in the period ended March 31, 2019, in conformity with U.S. generally accepted accounting principles.

**Basis for Opinion**

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2007.

Belfast, United Kingdom  
May 29, 2019

---

QUOTIENT LIMITED

CONSOLIDATED BALANCE SHEETS

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

	March 31, 2019	March 31, 2018
<b>ASSETS</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 4,096	\$ 20,165
Short-term investments	90,729	5,669
Trade accounts receivable, net	3,348	2,862
Inventories	15,551	16,278
Prepaid expenses and other current assets	3,202	7,065
<b>Total current assets</b>	<b>116,926</b>	<b>52,039</b>
Restricted cash	7,507	5,040
Property and equipment, net	47,293	60,156
Intangible assets, net	751	914
Deferred income taxes	605	649
Other non-current assets	4,688	5,043
<b>Total assets</b>	<b>\$ 177,770</b>	<b>\$ 123,841</b>
<b>LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)</b>		
<b>Current liabilities:</b>		
Accounts payable	\$ 5,936	\$ 5,441
Accrued compensation and benefits	6,149	5,312
Accrued expenses and other current liabilities	12,458	15,340
Current portion of deferred lease rental benefit	435	443
Current portion of capital lease obligation	471	515
<b>Total current liabilities</b>	<b>25,449</b>	<b>27,051</b>
Long-term debt, less current portion	121,855	85,063
Deferred lease rental benefit, less current portion	1,144	443
Capital lease obligation, less current portion	865	1,422
Defined benefit pension plan obligation	7,368	6,168
7% Cumulative redeemable preference shares	19,375	18,325
<b>Total liabilities</b>	<b>176,056</b>	<b>138,472</b>
Commitments and contingencies	—	—
<b>Shareholders' equity (deficit):</b>		
Ordinary shares (nil par value) 65,900,447 and 45,646,424 issued and outstanding at March 31, 2019 and March 31, 2018 respectively	368,958	253,934
Additional paid in capital	28,665	23,708
Accumulated other comprehensive loss	(14,884)	(16,634)
Accumulated deficit	(381,025)	(275,639)
<b>Total shareholders' equity (deficit)</b>	<b>1,714</b>	<b>(14,631)</b>
<b>Total liabilities and shareholders' equity (deficit)</b>	<b>\$ 177,770</b>	<b>\$ 123,841</b>

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

**CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

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

	Year ended March 31,		
	2019	2018	2017
<b>Revenue:</b>			
Product sales	\$ 28,665	\$ 23,913	\$ 20,127
Other revenues	469	819	2,100
<b>Total revenue</b>	<u>29,134</u>	<u>24,732</u>	<u>22,227</u>
Cost of revenue	(17,230)	(10,471)	(10,844)
<b>Gross profit</b>	11,904	14,261	11,383
<b>Operating expenses:</b>			
Sales and marketing	(8,637)	(7,347)	(5,660)
Research and development, net of government grants	(50,677)	(51,202)	(57,064)
<b>General and administrative expense:</b>			
Compensation expense in respect of share options and management equity incentives	(4,957)	(4,156)	(4,221)
Other general and administrative expenses	(26,588)	(21,544)	(18,497)
Total general and administrative expense	(31,545)	(25,700)	(22,718)
<b>Total operating expense</b>	<u>(90,859)</u>	<u>(84,249)</u>	<u>(85,442)</u>
<b>Operating loss</b>	(78,955)	(69,988)	(74,059)
<b>Other income (expense):</b>			
Interest expense, net	(20,018)	(15,365)	(9,903)
Other, net	(6,369)	2,366	(1,107)
<b>Other income (expense), net</b>	<u>(26,387)</u>	<u>(12,999)</u>	<u>(11,010)</u>
<b>Loss before income taxes</b>	(105,342)	(82,987)	(85,069)
Provision for income taxes	(44)	649	—
<b>Net loss</b>	<u>\$ (105,386)</u>	<u>\$ (82,338)</u>	<u>\$ (85,069)</u>
<b>Other comprehensive income (loss):</b>			
Change in fair value of effective portion of foreign currency cash flow hedges	\$ (123)	\$ 305	\$ (63)
Unrealized gain on short-term investments	796	6	19
Foreign currency gain (loss)	1,964	2,240	(6,215)
Provision for pension benefit obligation	(887)	107	(410)
<b>Other comprehensive loss, net</b>	<u>1,750</u>	<u>2,658</u>	<u>(6,669)</u>
<b>Comprehensive loss</b>	<u>\$ (103,636)</u>	<u>\$ (79,680)</u>	<u>\$ (91,738)</u>
Net loss available to ordinary shareholders - basic and diluted	\$ (105,386)	\$ (82,338)	\$ (85,069)
Loss per share - basic and diluted	\$ (1.92)	\$ (2.02)	\$ (3.02)
Weighted-average shares outstanding - basic and diluted	54,874,391	40,839,309	28,145,472

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

**CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY (DEFICIT)**  
(Expressed in thousands of U.S. Dollars — except for share data)

	Ordinary shares		Additional paid in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Shareholders' Equity (Deficit)
	Shares	Amount				
<b>March 31, 2016</b>	25,408,950	\$ 155,914	\$ 11,664	\$ (12,623)	\$ (108,232)	\$ 46,723
Issue of shares, net of issue costs of \$1,348	3,270,000	16,682	—	—	—	16,682
Exercise of pre-funded warrants	850,000	9	—	—	—	9
Issue of shares upon exercise of incentive share options and vesting of RSUs	38,748	12	—	—	—	12
Net loss	—	—	—	—	(85,069)	(85,069)
Change in the fair value of the effective portion of cash flow hedges	—	—	—	(63)	—	(63)
Change in unrealized gain on short-term investments	—	—	—	19	—	19
Foreign currency gain (loss) on:						
Long-term investment nature intra-entity balances	—	—	—	6,747	—	6,747
Retranslation of foreign entities	—	—	—	(12,962)	—	(12,962)
Provision for pension benefit obligation	—	—	—	(410)	—	(410)
Other comprehensive loss	—	—	—	(6,669)	—	(6,669)
Stock-based compensation	—	—	4,221	—	—	4,221
<b>March 31, 2017</b>	29,567,698	\$ 172,617	\$ 15,885	\$ (19,292)	\$ (193,301)	\$ (24,091)
Issue of shares, net of issue costs of \$680	15,914,683	81,206	—	—	—	81,206
Issue of shares upon exercise of incentive share options and vesting of RSUs	164,043	111	—	—	—	111
Issue of warrants	—	—	3,667	—	—	3,667
Net loss	—	—	—	—	(82,338)	(82,338)
Change in the fair value of the effective portion of cash flow hedges	—	—	—	305	—	305
Change in unrealized gain on short-term investments	—	—	—	6	—	6
Foreign currency gain (loss) on:						
Long-term investment nature intra-entity balances	—	—	—	(9,105)	—	(9,105)
Retranslation of foreign entities	—	—	—	11,345	—	11,345
Provision for pension benefit obligation	—	—	—	107	—	107
Other comprehensive loss	—	—	—	2,658	—	2,658
Stock-based compensation	—	—	4,156	—	—	4,156
<b>March 31, 2018</b>	45,646,424	\$ 253,934	\$ 23,708	\$ (16,634)	\$ (275,639)	\$ (14,631)
Issue of shares, net of issue costs of \$4,502	19,635,068	113,724	—	—	—	113,724
Issue of shares upon exercise of incentive share options and vesting of RSUs	618,955	1,300	—	—	—	1,300
Net loss	—	—	—	—	(105,386)	(105,386)
Change in the fair value of the effective portion of cash flow hedges	—	—	—	(123)	—	(123)
Change in unrealized gain on short-term investments	—	—	—	796	—	796
Foreign currency gain (loss) on:						
Long-term investment nature intra-entity balances	—	—	—	5,074	—	5,074
Retranslation of foreign entities	—	—	—	(3,110)	—	(3,110)
Provision for pension benefit obligation	—	—	—	(887)	—	(887)
Other comprehensive loss	—	—	—	1,750	—	1,750
Stock-based compensation	—	—	4,957	—	—	4,957
<b>March 31, 2019</b>	65,900,447	\$ 368,958	\$ 28,665	\$ (14,884)	\$ (381,025)	\$ 1,714

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

**CONSOLIDATED STATEMENTS OF CASH FLOWS**  
(Expressed in thousands of U.S. Dollars)

	Year ended March 31,		
	2019	2018	2017
<b>OPERATING ACTIVITIES:</b>			
Net loss	\$ (105,386)	\$ (82,338)	\$ (85,069)
<b>Adjustments to reconcile net loss to net cash provided by operating activities:</b>			
Depreciation, amortization and loss on disposal of fixed assets	12,767	10,405	9,461
Share-based compensation	4,957	4,156	4,221
Amortization of lease incentive	372	(435)	(428)
Swiss pension obligation	575	659	616
Amortization of deferred debt issue costs and fee paid to noteholders	5,908	4,359	6,774
Accrued preference share dividends	1,050	1,050	1,050
Deferred income taxes	44	(649)	—
<b>Net change in assets and liabilities:</b>			
Trade accounts receivable, net	(637)	(87)	(584)
Inventories	(93)	(1,741)	(1,766)
Accounts payable and accrued liabilities	370	(3,310)	9,960
Accrued compensation and benefits	1,121	1,596	778
Other assets	3,297	(2,083)	(1,213)
<b>Net cash used in operating activities</b>	<b>(75,655)</b>	<b>(68,418)</b>	<b>(56,200)</b>
<b>INVESTING ACTIVITIES:</b>			
Increase in short-term investments	(119,000)	(78,000)	(30,009)
Realization of short-term investments	34,735	88,395	13,971
Purchase of property and equipment	(4,791)	(21,604)	(20,155)
Sale of property and equipment	—	19,741	—
Payment of rent deposit	—	(5,043)	—
Purchase of intangible assets	(3)	(150)	(71)
<b>Net cash from (used in) investing activities</b>	<b>(89,059)</b>	<b>3,339</b>	<b>(36,264)</b>
<b>FINANCING ACTIVITIES:</b>			
Repayment of finance leases	(486)	(1,692)	(141)
Proceeds from drawdown of new debt	36,000	—	84,000
Repayment of debt	—	—	(33,450)
Debt issuance costs	(1,216)	—	(5,530)
Fees paid to noteholders	(3,900)	—	—
Proceeds from issuance of ordinary shares and warrants	115,024	84,984	16,703
<b>Net cash generated from financing activities</b>	<b>145,422</b>	<b>83,292</b>	<b>61,582</b>
Effect of exchange rate fluctuations on cash, cash equivalents and restricted cash	5,690	(2,802)	(3,424)
Change in cash, cash equivalents and restricted cash	(13,602)	15,411	(34,306)
Beginning cash, cash equivalents and restricted cash	25,205	9,794	44,100
Ending cash, cash equivalents and restricted cash	<u>\$ 11,603</u>	<u>\$ 25,205</u>	<u>\$ 9,794</u>
<b>Supplemental cash flow disclosures:</b>			
Income taxes paid	\$ —	\$ —	\$ —
Interest paid	\$ 11,838	\$ 10,144	\$ 1,702
<b>Reconciliation of cash, cash equivalents and restricted cash:</b>			
Cash and cash equivalents	\$ 4,096	\$ 20,165	\$ 4,754
Restricted cash	7,507	5,040	5,040
Total cash, cash equivalents and restricted cash	<u>\$ 11,603</u>	<u>\$ 25,205</u>	<u>\$ 9,794</u>

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

## NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

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

### Note 1. Organization and Summary of Significant Accounting Policies

#### Organization and Business

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

The Company has incurred net losses and negative cash flows from operations in each year since it commenced operations in 2007 and had an accumulated deficit of \$381.0 million as of March 31, 2019. At March 31, 2019, the Company had available cash holdings and short-term investments of \$94.8 million and, on May 15, 2019, the date of issuance of an additional \$25 million of the Company's 12% Senior Secured Notes due 2024 (the "Secured Notes"), it received a further \$22.6 million in available cash, net of expenses. The Company's existing available cash and short-term investment balances are adequate to meet its forecasted cash requirements for the next twelve months and accordingly the financial statements have been prepared on the going concern basis.

In the longer term, the Company expects to fund its operations, including the ongoing development of MosaiQ through successful field trial completion, achievement of required regulatory authorizations and commercialization from the use of existing available cash and short-term investment balances and the issuance of new equity or debt.

#### Summary of Significant Accounting Policies

##### *Principles of Consolidation*

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

##### *Use of Estimates*

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

##### *Fair Value of Financial Instruments*

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. The Company's valuation techniques used to measure fair value maximized the use of observable inputs and minimized the use of unobservable inputs. The fair value hierarchy is based on the following three levels of inputs:

- Level 1—Quoted prices in active markets for identical assets or liabilities.
- Level 2—Inputs other than Level 1 that are observable, either directly or indirectly, such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3—Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities.

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

#### ***Cash and Cash Equivalents***

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. As of March 31, 2019 and 2018, all cash and cash equivalents comprised cash balances held with the banks used by the Company and its subsidiaries. At March 31, 2019 and March 31, 2018, restricted cash comprised \$7.2 million and \$5.0 million, respectively, held in a cash reserve account pursuant to the indenture governing the Secured Notes and \$307 at March 31, 2019 held in a restricted account as security for the property rental obligations of the Company's Swiss subsidiary.

#### ***Short-term Investments***

Short-term investments represent investments in a money-market fund which is valued daily and which has no minimum notice period for withdrawals. The fund is invested in a portfolio of holdings and the creditworthiness requirement for individual investment holdings is a minimum of an A rating from a leading credit-rating agency. The Company records the value of its investment in the fund based on the quoted value of the fund at the balance sheet date. Unrealized gains or losses are recorded in accumulated other comprehensive loss and are transferred to the statement of comprehensive loss when they are realized.

#### ***Trade Accounts Receivable***

Trade accounts receivable are recorded at the invoiced amount and are not interest bearing. The Company maintains an allowance for doubtful accounts to reserve for potentially uncollectible trade receivables. Additions to the allowance for doubtful accounts are recorded as general and administrative expenses. The Company reviews its trade receivables to identify specific customers with known disputes or collectability issues. In addition, the Company maintains an allowance for all other receivables not included in the specific reserve by applying specific rates of projected uncollectible receivables to the various aging categories. In determining these percentages, the Company analyzes its historical collection experience, customer credit-worthiness, current economic trends and changes in customer payment terms. The allowance for doubtful accounts at March 31, 2019 and 2018 was \$52 and \$93, respectively.

#### ***Concentration of Credit Risks and Other Uncertainties***

The carrying amounts for financial instruments consisting of cash and cash equivalents, accounts receivable, accounts payable and accrued liabilities approximate fair value due to their short maturities. Derivative instruments, consisting of foreign exchange contracts and short-term investments are stated at their estimated fair values, based on quoted market prices for the same or similar instruments. The counterparties to the foreign exchange contracts consist of large financial institutions of high credit standing. The short-term investments are invested in a fund which is invested in a portfolio of holdings and the creditworthiness requirement for individual investment holdings is a minimum of an A rating from a leading credit-rating agency.

The Company's main financial institutions for banking operation held all of the Company's cash and cash equivalents as of March 31, 2019 and March 31, 2018.

The Company's accounts receivable are derived from net revenue to customers and distributors located in the United States and other countries. The Company performs credit evaluations of its customers' financial condition. The Company provides reserves for potential credit losses but has not experienced significant losses to date. There was one customer whose accounts receivable balance represented 10% or more of total accounts receivable, net, as of March 31, 2019 and March 31, 2018. This customer represented 55% and 51% of the accounts receivable balances, as of March 31, 2019 and March 31, 2018, respectively.

The Company currently sells products through its direct sales force and through third-party distributors. There was one direct customer that accounted for 10% or more of total product sales for the fiscal years ended March 31, 2019, 2018 and 2017. This customer represented 60%, 63% and 60% of total product sales for the fiscal years March 31, 2019, 2018 and 2017, respectively.

#### ***Inventory***

Inventory is stated at the lower of standard cost (which approximates actual cost) or market, with cost determined on the first-in-first-out method. Accordingly, allocation of fixed production overheads to conversion costs is based on normal capacity of production. Abnormal amounts of idle facility expense, freight, handling costs and spoilage are expensed as incurred and not included in overhead. No stock-based compensation cost was included in inventory as of March 31, 2019 and 2018.



### ***Property and Equipment***

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

- Land—not depreciated.
- Plant, machinery and equipment—4 to 25 years;
- Leasehold improvements—the shorter of the lease term or the estimated useful life of the asset.

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

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by comparing the carrying amount of the assets to the future undiscounted cash flows expected to be generated by the assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. During the fiscal years ended March 31, 2019, 2018 and 2017, no impairment losses have been recorded.

### ***Intangible Assets and Goodwill***

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

Customer relationships—5 years

Brands associated with acquired cell lines—40 years

Product licenses—10 years

Other intangibles—7 years

The Company reviews its intangible assets for impairment and conducts the impairment review when events or circumstances indicate the carrying value of a long-lived asset may be impaired by estimating the future undiscounted cash flows to be derived from an asset to assess whether or not a potential impairment exists. If the carrying value exceeds the Company's estimate of future undiscounted cash flows, an impairment value is calculated as the excess of the carrying value of the asset over the Company's estimate of its fair market value. Events or circumstances which could trigger an impairment review include a significant adverse change in the business climate, an adverse action or assessment by a regulator, unanticipated competition, significant changes in the Company's use of acquired assets, the Company's overall business strategy, or significant negative industry or economic trends. No impairment losses have been recorded in any of the years ended March 31, 2019, 2018 or 2017.

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

### ***Revenue Recognition***

Revenue is recognized in accordance with ASU 2014-09, *Revenue from Contracts with Customers*.

Product revenue is recognized at a point in time upon transfer of control of a product to a customer, which is generally at the time of delivery at an amount based on the transaction price. Customers have no right of return except in the case of damaged goods and the Company has not experienced any significant returns of its products. Shipping and handling costs are expensed as incurred and included in cost of product sales. In those cases where the Company bills shipping and handling costs to customers, the amounts billed are classified as revenue.

Revenue is also earned from the provision of development services to a small number of original equipment manufacturer (“OEM”) customers. These development service contracts are reviewed individually to determine the nature of the performance obligations and the associated transaction prices. In recent years, product development revenues have been commensurate with achieving milestones specified in the respective development agreements relating to those products. These milestones may include the approval of new products by the European or U.S. regulatory authorities, which are not within the Company’s control. While there can be no assurance that this will continue to be the case, the milestones have been such that they effectively represent completion of our performance obligations under a particular part of a development program. Should we fail to achieve these milestones we would not be entitled under the terms of the development agreements to any compensation for the work undertaken to date. As a result, the milestone-related revenues have been recognized as the contractual milestones are achieved.

Pursuant to an Umbrella Supply Agreement with Ortho-Clinical Diagnostics, Inc. (“Ortho”), the Company executed a product attachment relating to the development of a range of rare antisera products. During the year ended March 31, 2018, the Company recognized a milestone of \$600 related to the receipt of FDA approval of certain rare antisera products and during the year ended March 31, 2019, the Company recognized a milestone of \$450 related to the submission to the FDA of an application to cover use of the products on an Ortho automation platform. The Company is entitled to receive further milestone payments totalling \$1,050 related to FDA submissions and approvals of the use of the products on Ortho’s automation platforms. The Company expects these remaining milestones to be achieved in the next financial year.

In January 2015, the Company entered into a supply and distribution agreement with Ortho related to the commercialization and distribution of certain MosaiQ products. Under the terms of this agreement, the Company is entitled to receive milestone payments upon CE-mark and FDA approval, as well as upon the first commercial sale of the relevant MosaiQ products by Ortho within the European Union, United States and within any country outside of these two regions. The Company has concluded that as each of these milestones require significant levels of development work to be undertaken and there was no certainty at the start of the projects if or when the development work would be successful, these milestones are substantive and the revenue will be recognized when the milestones are achieved.

In the years ended March 31, 2019, 2018 and 2017 revenue recognized from performance obligations related to prior periods was not material and, at March 31, 2019, revenue expected to be recognized in future periods related to remaining performance obligations was also not material.

#### ***Research and Development***

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

#### ***Stock-Based Compensation***

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

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

Where modifications are made to vesting conditions, as happened during the year ended March 31, 2018 upon the retirement of Paul Cowan, the Company’s former Chief Executive Officer, the Company considers the nature of the change and accounts for the change in accordance with ASC 715 *Compensation – Stock Compensation*. The Company determined that the modification to Mr. Cowan’s awards were type III in nature and accordingly the original compensation expense related to the awards was reversed and the value of the awards was re-measured at the date of the change and was expensed over the vesting period of the awards concerned.

### **Share Warrants**

As of March 31, 2019, the Company had one class of warrants to purchase ordinary shares outstanding which comprised warrants that were issued in December 2013 and August 2015 in connection with the establishment and subsequent increase of the Company's then existing secured term loan facility. None of these warrants contain any obligation to transfer value and, as such, the issuance of these warrants has been recorded in additional paid in capital as part of shareholders' equity.

### **Leases**

At the inception of each lease, the Company reviews the terms of the lease in accordance with ASC 840 *Leases* in order to determine whether the lease concerned is a capital or an operating lease. In the case of capital leases, an asset is included within property and equipment and a lease liability equal to the present value of the minimum lease payments is included in current or long-term liabilities. Interest expense is recorded over the life of the lease at a constant rate.

Rentals relating to operating leases are expensed over the life of the lease. Rental incentives and the gain on the sale and leaseback of the manufacturing facility near Edinburgh, Scotland completed in March 2018 are included within deferred lease rental benefit in the balance sheet and amortized over the life of the related lease.

### **Derivative Financial Instruments**

In the normal course of business, the Company's financial position is routinely subjected to market risk associated with foreign currency exchange rate fluctuations. The Company's policy is to mitigate the effect of these exchange rate fluctuations on certain foreign currency denominated business exposures. The Company has a policy that allows the use of derivative financial instruments to hedge foreign currency exchange rate fluctuations on forecasted revenue denominated in foreign currencies. The Company carries derivative financial instruments (derivatives) on the balance sheet at their fair values. The Company does not use derivatives for trading or speculative purposes. The Company does not believe that it is exposed to more than a nominal amount of credit risk in its foreign currency hedges, as counterparties are large, global and well-capitalized financial institutions. To hedge foreign currency risks, the Company uses foreign currency exchange forward contracts, where possible and prudent. These forward contracts are valued using standard valuation formulas with assumptions about future foreign currency exchange rates derived from existing exchange rates, interest rates, and other market factors.

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

### **Income Taxes**

The Company accounts for income taxes using an asset and liability approach, which requires recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the consolidated financial statements, but have not been reflected in taxable income. A valuation allowance is established to reduce deferred tax assets to their estimated realizable value. Therefore, the Company provides a valuation allowance to the extent that it is more likely than not that it will generate sufficient taxable income in future periods to realize the benefit of its deferred tax assets. Deferred tax assets and liabilities are classified as noncurrent on the balance sheet.

On December 22, 2017, the Tax Cuts and Jobs Act of 2017, or the TCJA, was enacted. This tax reform legislation made significant changes in U.S. tax law including a reduction in the corporate tax rates, changes to net operating loss carryforwards and carrybacks, and a repeal of the corporate alternative minimum tax. The legislation reduced the U.S. corporate tax rate from the rate of 35% to 21% effective on January 1, 2018. As a result, the Company revalued its U.S. deferred tax assets and liabilities at the 21% rate with effect from January 1, 2018. This revaluation and also the other provisions of the TCJA did not have a material impact on the Company's consolidated financial statements.

### **Pension Obligation**

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

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

#### ***Debt Issuance Costs and Royalty Rights***

The Company follows the requirements of Accounting Standards Update 2015-03, Interest — Imputation of Interest (Subtopic 835-30) — Simplifying the Presentation of Debt Issuance Costs, which requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the debt liability rather than as an asset.

The royalty rights agreements entered into with subscribers to the October 14, 2016 and June 29, 2018 issuances of the Secured Notes are treated as sales of future revenues that meet the requirements of Accounting Standards Codification Topic 470 "Debt" ("ASC 470") to be treated as debt. The future cash outflows under the royalty rights agreements have been combined with the issuance costs and interest payable to calculate the effective interest rate of the Secured Notes and is being expensed through interest expense in the consolidated statement of comprehensive loss using the effective interest rate method over the term of the Secured Notes and royalty rights agreements.

On December 18, 2018, the Company completed certain amendments to the indenture governing the Secured Notes. These amendments included a six-month extension of the final maturity of the Secured Notes to April 2024 and a revision of the Secured Notes' principal amortization (previously scheduled to commence semi-annually beginning April 2019) to commence April 2021, in order to better align the maturity and amortization schedule with the Company's financial goals. The revised amortization schedule deferred approximately \$39.6 million of principal amortization previously scheduled to occur between April 2019 and April 2021. In addition, the amendments included a one-year extension of the optional redemption call schedule to October 2022. In consideration for the consents to the amendments, the Company paid to the noteholders a one-time consent payment of \$3.9 million and it issued additional royalty rights to the noteholders, which increased in the aggregate the amount of the royalties payable under the royalty rights that were previously issued by the Company in connection with the prior issuances of the Secured Notes by 1%, from 2% to 3%, of the aggregate net sales of MosaiQ instruments and consumables in specified markets.

The amendments to the maturity of the Secured Notes have been evaluated as a modification of the terms of the debt under ASC 470 and accordingly the consent payment of \$3.9 million and the increase in the royalty rights have been added to the costs of the October 2016 and June 2018 debt issuances of the Secured Notes and will be expensed through interest expense in the consolidated statement of comprehensive loss using the effective interest rate method over the term of the Secured Notes and royalty rights agreements.

#### ***Adoption of New Accounting Standards***

In May 2014, the FASB issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, or ASU 2014-09. Under ASU 2014-09, a company should recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the company expects to be entitled in exchange for those goods or services. In addition, ASU 2014-09 requires certain additional disclosures around the nature, amount, timing, and uncertainty of revenue and cash flows arising from contracts with customers. The FASB has issued several amendments to the standard, including clarification on accounting for licenses of intellectual property, identifying performance obligations and other technical corrections. The Company adopted ASU 2014-09 on April 1, 2018, using the modified retrospective approach. The adoption of ASU 2014-09 did not have a material impact on the Company's financial position, results of operations, equity or cash flows as of the adoption date or for the year ended March 31, 2019.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows: Restricted Cash*, or ASU 2016-18. ASU 2016-18 requires amounts generally described as restricted cash and restricted cash equivalents be included with cash and cash equivalents when reconciling the total beginning and ending amounts for the periods shown on the statement of cash flows. ASU 2016-18 is effective for fiscal years beginning after December 15, 2017 (including interim periods within) using a retrospective transition method to each period presented. The Company adopted ASU 2016-18 retrospectively as of April 1, 2018. The adoption of ASU 2016-18 resulted in restricted cash of \$5,040 being included in the ending amounts of cash and cash equivalents for both the year ended March 31, 2018 and the year ended March 31, 2017 on the Company's consolidated statement of cash flows.

In March 2017, the FASB issued ASU 2017-07 *Compensation-Retirement Benefits*, or ASU 2017-07, in order to improve the presentation of net periodic pension cost and net periodic postretirement benefit cost in the statements of operations. Under ASU 2017-07, the service cost component of the net periodic benefit cost is disclosed in the same income statement line item as other employee compensation costs arising from services rendered during the period, and the other components are reported separately from the line item that includes the service cost and outside of any subtotal of operating income. ASU 2017-07 is effective for annual periods beginning after December 15, 2017 (including interim periods within) using a retrospective transition method to each period presented. The Company adopted the provisions of ASU 2017-07 on April 1, 2018 and applied the change retrospectively in its consolidated statement of comprehensive loss using the practical expedient. The adoption of ASU 2017-07 has not had a material impact on the Company's consolidated statement of comprehensive loss.

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

#### **Recent Accounting Pronouncements Not Yet Adopted**

In February 2016, the FASB issued ASU 2016-02, *Leases* or ASU 2016-02. ASU 2016-02 requires lessees to recognize a right-of-use asset and a lease liability on their balance sheet for all leases with lease terms greater than 12 months but recognize expenses in their income statements in a manner similar to current accounting standards. ASU 2016-02 will also require new qualitative and quantitative disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. ASU 2016-02 is effective for annual periods beginning after December 15, 2018, including interim periods within those fiscal years, with early adoption permitted. The Company will adopt the new standard effective as of April 1, 2019.

In adopting this standard the Company expects to apply the package of practical expedients in ASU 2016-02 which allow an entity to not reassess whether any expired or existing contracts are or contain leases, lease classification of any expired or existing leases and the accounting for any initial direct costs on any expired or existing leases. The Company also expects to elect the additional transitional approach prescribed under ASU 2018-11 to allow the Company to apply the new standard from the date of adoption, rather than adjusting comparative periods, and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company has completed its review of the existing portfolio of leases. The Company does not expect any material impact on its consolidated statements of comprehensive loss but does expect to recognize approximately \$18.9 million of right-of-use assets and associated lease liabilities of a similar amount to its consolidated balance sheet in respect of its existing operating lease arrangements.

In August 2018, the FASB issued ASU 2018-14, "*Compensation Retirement Benefits - Defined Benefit Plans -General (Subtopic 715-20)*" or ASU 2018-14. ASU 2018-14 removes the requirements to disclose the amounts in Accumulated other comprehensive income (loss) expected to be recognized as components of net periodic benefit cost over the next fiscal year and other disclosure requirements. In addition, the ASU adds the requirement to disclose an explanation for any significant gains and losses related to changes in the benefit obligation for the period. The ASU is effective for fiscal years ending after December 15, 2020 and will be applied on a retrospective basis to all periods presented. Early adoption is permitted. The Company continues to evaluate the impact that adoption of this guidance will have on its consolidated financial statements and related disclosures, but does not expect it to have a material impact.

#### **Note 2. Intangible Assets**

	March 31, 2019			
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Remaining Useful Life
Customer relationships	\$ 2,564	\$ (2,564)	\$ —	—
Brands associated with acquired cell lines	529	(153)	376	28.4 years
Product licenses	890	(515)	375	4.2 years
Other intangibles	167	(167)	—	—
Total	<u>\$ 4,150</u>	<u>\$ (3,399)</u>	<u>\$ 751</u>	16.3 years

March 31, 2018				
	Gross Carrying Amount	Accumulated Amortization	Net Carrying Amount	Weighted Average Remaining Useful Life
Customer relationships	\$ 2,758	\$ (2,758)	\$ —	—
Brands associated with acquired cell lines	569	(150)	419	29.5 years
Product licenses	954	(459)	495	5.2 years
Other intangibles	179	(179)	—	—
<b>Total</b>	<b>\$ 4,460</b>	<b>\$ (3,546)</b>	<b>\$ 914</b>	<b>16.3 years</b>

Amortization expense was \$104, \$94, and \$73 in financial years 2019, 2018, and 2017, respectively. Total future amortization expense for intangible assets that have definite lives, based upon the Company's existing intangible assets and their current estimated useful lives as of March 31, 2019, is estimated as follows:

2019	\$ 102
2020	102
2021	102
2022	102
2023	57
Thereafter	286
<b>Total</b>	<b>\$ 751</b>

### Note 3. Debt

Long-term debt comprises:

	March 31, 2019	March 31, 2018
Total debt	\$ 120,000	\$ 84,000
Less current portion	—	—
Long-term debt	\$ 120,000	\$ 84,000
Deferred debt costs and royalty liability, net of amortization	1,855	1,063
	<u>\$ 121,855</u>	<u>\$ 85,063</u>

The Company's debt at March 31, 2019 and March 31, 2018 comprises the 12% Senior Secured Notes. On October 14, 2016, the Company completed the private placement of up to \$120 million aggregate principal amount of the Secured Notes and entered into an indenture governing the Secured Notes with the guarantors party thereto and U.S. Bank National Association, a national banking association, as trustee and collateral agent. The Company issued \$84 million aggregate principal amount of the Secured Notes on October 14, 2016 and an additional \$36 million aggregate principal amount of the Secured Notes on June 29, 2018. On December 18, 2018, the Company also completed certain amendments to the indenture governing the Secured Notes. The amendments included an increase to the aggregate principal amount of Secured Notes that can be issued under the indenture from \$120.0 million to up to \$145.0 million following the European CE Marking of the Company's initial MosaiQ IH Microarray. Furthermore, on January 15, 2019 the Company entered into purchase agreements pursuant to which the Company agreed to issue and certain purchasers agreed to purchase the additional \$25 million of the Secured Notes (the "CE Marking Notes"). On May 15, 2019, the CE Marking Notes were issued.

Furthermore, the obligations of the Company under the indenture and the Secured Notes are unconditionally guaranteed on a secured basis by the guarantors, which include all the Company's subsidiaries, and the indenture governing the Secured Notes contains customary events of default. The Company and its subsidiaries must also comply with certain customary affirmative and negative covenants, including a requirement to maintain six-months of interest in a cash reserve account maintained with the collateral agent. Upon the occurrence of a Change of Control, subject to certain conditions, or certain Asset Sales (each, as defined in the indenture), holders of the Secured Notes may require the Company to repurchase for cash all or part of their Secured Notes at a repurchase price equal to 101% or 100%, respectively, of the principal amount of the Secured Notes to be repurchased, plus accrued and unpaid interest to the date of repurchase.

The Company paid \$7.2 million of the total proceeds of the October 2016 and June 2018 issuances into the cash reserve account maintained with the collateral agent under the terms of the indenture, \$2.2 million of which related to the second issuance. It paid a further \$1.5 million into the cash reserve account in May 2019 in connection with the issuance of the CE Marking Notes.

Interest on the Secured Notes accrues at a rate of 12% per annum and is payable semi-annually on April 15 and October 15 of each year commencing on April 15, 2017. Commencing on April 15, 2021, the Company will also pay an instalment of principal of the Secured Notes on each April 15 and October 15 until April 15, 2024 pursuant to a fixed amortization schedule.

In connection with the October 2016 and June 2018 issuances of the Secured Notes as well as the December 2018 amendment of the related indenture, the Company has entered into royalty rights agreements, pursuant to which the Company has agreed to pay 3.0% of the aggregate net sales of MosaiQ instruments and consumables made in the donor testing market in the United States and the European Union. Further, in connection with the issuance of the CE Marking Notes in May 2019, the Company has also entered into royalty rights agreements, pursuant to which the Company has agreed to pay an additional 0.4% of such net sales. The royalties will be payable beginning on the date that the Company or its affiliates makes its first sale of MosaiQ consumables in the donor testing market in the European Union or the United States and will end on the last day of the calendar quarter in which the eighth anniversary of the first sale date occurs. The royalty rights agreements are treated as sales of future revenues that meet the requirements of Accounting Standards Codification Topic 470 "Debt" to be treated as debt. The future cash outflows under the royalty rights agreements, estimated at \$74.4 million at March 31, 2019 and \$41.8 million at March 31, 2018, have been combined with the Secured Notes issuance costs and interest payable to calculate the effective interest rate of the Secured Notes and will be expensed through interest expenses using the effective interest rate method over the term of the Secured Notes and the royalty rights agreements. Estimating the future cash outflows under the royalty rights agreements requires the Company to make certain estimates and assumptions about future sales of MosaiQ products. These estimates of the magnitude and timing of MosaiQ sales are subject to significant variability due to the current status of development of MosaiQ products, and thus are subject to significant uncertainty. Therefore, the estimates are likely to change as the Company gains experience of marketing MosaiQ, which may result in future adjustments to the accretion of the interest expense and amortized cost based carrying value of the Secured Notes.

The outstanding debt at March 31, 2019 falls due for repayment as follows:

Within 1 year	\$	—
Between 1 and 2 years		—
Between 2 and 3 years		20,000
Between 3 and 4 years		35,000
Between 4 and 5 years		40,000
After 5 years		25,000
Total debt	\$	<u>120,000</u>

#### Note 4. Fair Value Measurements

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

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

	March 31, 2019			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Pension plan assets(1)	\$ —	\$ 10,416	\$ —	\$ 10,416
Short-term investments(2)	90,729	—	—	90,729
Total assets measured at fair value	<u>\$ 90,729</u>	<u>\$ 10,416</u>	<u>\$ —</u>	<u>\$ 101,145</u>
<b>Liabilities:</b>				
Foreign currency forward contracts(3)	\$ —	\$ 70	\$ —	\$ 70
Total liabilities measured at fair value	<u>\$ —</u>	<u>\$ 70</u>	<u>\$ —</u>	<u>\$ 70</u>

	March 31, 2018			
	Level 1	Level 2	Level 3	Total
<b>Assets:</b>				
Pension plan assets(1)	\$ —	\$ 9,616	\$ —	\$ 9,616
Short-term investments(2)	5,669	—	—	5,669
Foreign currency forward contracts(3)	—	118	—	118
<b>Total assets measured at fair value</b>	<b>\$ 5,669</b>	<b>\$ 9,734</b>	<b>\$ —</b>	<b>\$ 15,403</b>

	March 31, 2018			
	Level 1	Level 2	Level 3	Total
<b>Liabilities:</b>				
Foreign currency forward contracts(3)	\$ —	\$ 64	\$ —	\$ 64
<b>Total liabilities measured at fair value</b>	<b>\$ —</b>	<b>\$ 64</b>	<b>\$ —</b>	<b>\$ 64</b>

- (1) The fair value of pension plan assets has been determined as the surrender value of the portfolio of active insured employees held within the Swiss Life collective investment fund.
- (2) The fair value of short-term investments has been determined based on the quoted value of the units held in the money market fund at the balance sheet date. See Note 1, "Summary of Significant Accounting Policies – Short-term Investments".
- (3) The fair value of foreign currency forward contracts has been determined by calculating the present value of future cash flows, estimated using market-based observable inputs including forward and spot exchange rates and interest rate curves obtained from third party market price quotations.

#### Note 5. Consolidated Balance Sheet Detail

##### *Inventory*

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

	March 31, 2019	March 31, 2018
Raw materials	\$ 8,216	\$ 10,024
Work in progress	4,959	4,226
Finished goods	2,376	2,028
<b>Total inventories</b>	<b>\$ 15,551</b>	<b>\$ 16,278</b>

Inventory at March 31, 2019 included \$6,187 of raw materials, \$2,311 of work in progress and \$235 of finished goods related to the MosaiQ project. Inventory at March 31, 2018 included \$8,441 of raw materials, \$1,528 of work in progress, and \$389 of finished goods related to the MosaiQ project.

##### *Property and equipment*

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

	March 31, 2019	March 31, 2018
Plant and equipment	\$ 51,327	\$ 51,912
Leasehold improvements	32,047	34,611
<b>Total property and equipment</b>	<b>83,374</b>	<b>86,523</b>
Less: accumulated depreciation	(36,081)	(26,367)
<b>Total property and equipment, net</b>	<b>\$ 47,293</b>	<b>\$ 60,156</b>

Depreciation expenses were \$12,663, \$10,311, and \$9,375 in financial years 2019, 2018 and 2017, respectively.



#### *Accrued compensation and benefits*

Accrued compensation and benefits consist of the following:

	March 31, 2019	March 31, 2018
Salary and related benefits	\$ 638	\$ 455
Accrued vacation	495	504
Accrued payroll taxes	1,316	1,353
Accrued incentive payments	3,700	3,000
Total accrued compensation and benefits	<u>\$ 6,149</u>	<u>\$ 5,312</u>

#### *Accrued expenses and other current liabilities*

Accrued expenses and other current liabilities consist of the following:

	March 31, 2019	March 31, 2018
Accrued legal and professional fees	\$ 405	\$ 280
Accrued interest	6,628	4,612
Goods received not invoiced	1,337	1,272
Accrued capital expenditure	801	3,309
Other accrued expenses	3,287	5,867
Total accrued expenses and other current liabilities	<u>\$ 12,458</u>	<u>\$ 15,340</u>

At March 31, 2018, other accrued expenses included a value added tax liability of \$2,905 related to the completion of the sale of the Company's new conventional reagents manufacturing facility (the "ARC facility") in March 2018. There was an offsetting value added tax recoverable balance within prepaid expenses and other current assets at March 31, 2018. There were no equivalent amounts at March 31, 2019.

#### **Note 6. Commitments and Contingencies**

##### *Lease commitments*

The Company leases its facilities and certain equipment under operating leases that expire at various dates through 2052. Some of the leases contain renewal options, escalation clauses, rent concessions, and leasehold improvement incentives. Rent expense is recognized on a straight-line basis over the lease term. Rent expense was \$4,950, \$3,063 and \$2,928 in financial years ended March 31, 2019, 2018 and 2017, respectively.

The following is a schedule by years of minimum future rentals on non-cancelable operating leases as of March 31, 2019:

2020	\$ 3,387
2021	1,861
2022	1,858
2023	1,830
2024	1,841
Thereafter	71,507
Total minimum future lease payments	<u>\$ 82,284</u>

##### *Sale-leaseback transaction*

During the year ended March 31, 2018, the Company completed a sale-leaseback transaction and sold the ARC facility, but retained a leasehold interest as tenant of the property. The transaction resulted in net cash proceeds of \$19,741 and a gain of \$373 which has been deferred and recorded within accrued liabilities on the Consolidated Balance Sheet and will be amortized on a straight-line basis over the lease term as a reduction of the rental expense in the consolidated statements of comprehensive loss. Additionally, the lease

required the Company to provide a rental deposit of £3,600 which amounted to \$4,688 at March 31, 2019 and \$5,043 at March 31, 2018 which is included within other non-current assets in the Consolidated Balance Sheet.

The Company evaluated the transaction in accordance with ASC 840, *Leases*, considering the requirements for sale-leaseback treatment, including the transfer of all risks of ownership to the purchaser and whether the Company has any continuing involvement in the leased property. The Company also evaluated the property lease in accordance with ASC 840 and concluded that the lease of the property was an operating lease. Refer to *Lease commitments* above for the future minimum lease payments associated with all the Company's operating leases. In connection with this transaction, the Company has agreed to transfer tax allowances related to certain other property, plant and equipment to the purchaser. However, at March 31, 2019, the transfer of these allowances had not been completed and thus the effect of the transfer has not been reflected in the financial statements.

The Company has entered into capital leases for the purchase of equipment that has a gross cost and net book value of \$2,781 and \$2,137, respectively as of March 31, 2019 and \$3,130 and \$2,810, respectively as of March 31, 2018. The following is a schedule of future annual repayments on capital leases as of March 31, 2019:

2020	\$	471
2021		369
2022		306
2023		190
2024		—
Thereafter		—
<b>Total minimum future lease payments</b>	<b>\$</b>	<b><u>1,336</u></b>

#### ***Purchase obligations***

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

The following is a schedule by years of purchase obligations as of March 31, 2019:

2020	\$	14,635
2021		4,519
2022		10,538
2023		11,691
2024		19,431
Thereafter		18,360
<b>Total minimum future purchase obligations</b>	<b>\$</b>	<b><u>79,174</u></b>

#### ***Hedging arrangements***

The Company's subsidiary in the United Kingdom ("UK") has entered into three foreign currency forward contracts to sell \$500 and purchase pounds sterling at a rate of £1:\$1.3520 in each calendar month through June 2019, three contracts to sell \$500 in each calendar month from July 2019 through September 2019 at £1:\$1.3000 and three contracts to sell \$500 in each calendar month from October 2019 through December 2019 at £1:\$1.3180 as hedges of its U.S. dollar denominated revenues. The fair values of these contracts, and similar contracts in place at March 31, 2018, amounted to an asset of \$118 at March 31, 2018 and liabilities of \$70 and \$64 at March 31, 2019 and March 31, 2018, respectively.

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

At inception and at each quarter end, hedges are tested prospectively and retrospectively for effectiveness. Changes in the fair value of foreign currency forward contracts due to changes in time value are excluded from the assessment of effectiveness and are recognized in revenue in the current period. The change in time value related to these contracts was not material for all reported periods. To qualify for hedge accounting, the hedge relationship must meet criteria relating both to the derivative instrument and the hedged item. These criteria include identification of the hedging instrument, the hedged item, the nature of the risk being hedged and how the hedging instrument's effectiveness in offsetting the exposure to changes in the hedged item's cash flows will be measured. There were no gains or losses during the years ended March 31, 2019, March 31, 2018 or March 31, 2017 associated with ineffectiveness or forecasted transactions that failed to occur.

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

#### Note 7. Geographic Information

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

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

	2019	2018	2017
Revenue:			
United States	\$ 14,754	\$ 12,917	\$ 11,432
France	6,501	5,608	4,733
Japan	3,846	3,335	3,141
Other foreign countries (1)	4,033	2,872	2,921
	<u>\$ 29,134</u>	<u>\$ 24,732</u>	<u>\$ 22,227</u>

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

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

	March 31, 2019	March 31, 2018
Long-lived assets:		
United Kingdom	\$ 19,924	\$ 24,141
Switzerland	27,366	36,009
United States	3	6
	<u>\$ 47,293</u>	<u>\$ 60,156</u>

Other income (expense), net includes foreign exchange gains and losses arising on the settlement of transactions in currencies other than the functional currencies of the entity concerned and from retranslation of assets and liabilities denominated in foreign currencies at period end rates. In the year ended March 31, 2019, there was a loss of \$5,410 and in the years ended March 31, 2018 and March 31, 2017, the respective amounts were gains of \$2,366 and \$2,853.

#### Note 8. Ordinary and Preference Shares

##### Ordinary shares

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

	Shares Issued and Outstanding		Par value
	March 31, 2019	March 31, 2018	
Ordinary shares	65,900,447	45,646,424	\$ —
Total	<u>65,900,447</u>	<u>45,646,424</u>	<u>\$ —</u>

In the time period between March 31, 2018 and July 31, 2018, 8,414,683 warrants that were previously issued in connection with the Company's October 2017 private placement of ordinary shares were exercised for 8,414,683 ordinary shares at \$5.80 per share, which generated \$48.8 million of proceeds. On August 3, 2018, the Company entered into two subscription agreements with Franz Walt, the Company's Chief Executive Officer, and with Heino von Prondzynski, the Company's Chairman, pursuant to which the Company issued a combined total of 55,000 ordinary shares at a price of \$7.54 per share for aggregate proceeds of \$0.4 million. On December 11, 2018, the Company completed a public offering of 10,615,385 newly issued ordinary shares at a price of \$6.50 per share which raised \$69.0 million of gross proceeds before underwriting discounts and other offering expenses.

**Preference shares**

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

	Shares Issued and Outstanding		Liquidation amount per share	
	March 31, 2019	March 31, 2018	March 31, 2019	March 31, 2018
7% Cumulative Redeemable Preference shares	666,665	666,665	\$ 29.06	\$ 27.50
Total	<u>666,665</u>	<u>666,665</u>		

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

**Note 9. Share-Based Compensation**

The Company records share-based compensation expense in respect of options and restricted share units ("RSUs"), including multi-year performance based restricted share units ("MRSUs"), issued under its share incentive plans and in respect of deferred shares issued to employees. Share-based compensation expense amounted to \$4,957 in the year ended March 31, 2019, \$4,156 in the year ended March 31, 2018 and \$4,221 in the year ended March 31, 2017.

**Option Plans**

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

Each option may be exercised for one ordinary share of the Company.

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

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

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

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

Under the 2014 Plan, 1,500,000 ordinary shares were initially reserved for issuance. This number is subject to adjustment in the event of a recapitalization, share split, share consolidation, reclassification, share dividend or other change in the Company's capital structure and automatically increases annually on April 1 of each year. The number of shares reserved for issuance under the plan was also increased by 750,000 as a result of a resolution passed at the Annual Shareholder meeting held on October 28, 2016 and by a further 550,000 as a result of a resolution passed at the Annual Shareholder meeting held on October 31, 2018. The plan provides for the issuance of share options, restricted shares, RSUs (including MRSUs) or share appreciation rights ("SARs"). The Company has only issued options, RSUs and MRSUs under the plan prior to March 31, 2019. To the extent that an award terminates, or expires for any reason, then any shares subject to the award may be used again for new grants. However, shares which are (i) not issued or delivered as a result of the net settlement of outstanding SARs or options; (ii) used to pay the exercise price related to outstanding options; (iii) used to pay withholding taxes related to outstanding options or SARs; or (iv) repurchased on the open market with the proceeds from an option exercise, will not be available for grant under the 2014 Plan.

#### Share option activity

The following table summarizes share option activity:

	Number of Share Options Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Life (Months)
Outstanding — March 31, 2016	1,589,938	\$ 7.86	96
Granted	419,682	9.12	120
Exercised	(8,483)	1.44	—
Forfeited	(52,220)	12.50	—
Outstanding — March 31, 2017	1,948,917	\$ 8.04	90
Granted	406,480	6.93	120
Exercised	(36,240)	3.07	—
Forfeited	(222,874)	9.16	—
Outstanding — March 31, 2018	2,096,283	\$ 7.79	84
Granted	189,552	6.59	120
Exercised	(253,066)	5.14	—
Forfeited	(96,372)	12.69	—
Outstanding — March 31, 2019	1,936,397	\$ 7.77	78
Exercisable — March 31, 2019	1,410,178	\$ 8.02	69

The following table summarizes the options granted in the year ended March 31, 2019 with their exercise prices, the fair value of ordinary shares as of the applicable grant date, and the intrinsic value, if any:

Grant Date	Number of Options Granted	Exercise Price	Ordinary Shares Fair Value Per Share at Grant Date		Per Share Intrinsic Value of Options
April 1, 2018	30,000	\$ 4.71	\$ 4.71	\$ 2.99	
October 31, 2018	43,680	\$ 6.41	\$ 6.41	\$ 4.02	
October 31, 2018	45,872	\$ 6.54	\$ 6.41	\$ 4.00	
October 31, 2018	70,000	\$ 7.54	\$ 6.41	\$ 3.81	

#### Determining the fair value of share options

The fair value of each grant of share options was determined by the Company using the Black-Scholes options pricing model. The total fair value of option awards in the years ended March 31, 2019, March 31, 2018 and March 31, 2017 amounted to \$676, \$1,718 and \$1,379, respectively.

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

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

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

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

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

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

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

	Year ended March 31,		
	2019	2018	2017
Risk-free interest rate	3.08%	2.34%	1.98%
Expected lives (years)	6	6	3
Volatility	67.19%	66.03%	62.93%
Dividend yield	—	—	—
Grant date fair value (per share)	\$ 6.14	\$ 6.93	\$ 9.12
Number granted	189,552	406,480	419,682

#### **RSU and MRSU Activity**

A summary of the RSUs and MRSUs in issue at March 31, 2019 is as follows:

	Number of RSUs or MRSUs Outstanding	Weighted Average Remaining Vesting Period (Months)	Period in which the target must be achieved
RSUs subject to time based vesting	632,709	11	N/A
RSUs subject to milestone based vesting	227,980	N/A	N/A
MRSUs with vesting based on \$22 share price	106,000	N/A	Apr - Dec 2019

At March 31, 2019, 632,709 RSUs were subject to time based vesting and the weighted average remaining vesting period was 11 months. In addition, 227,980 RSUs were subject to vesting based on the achievement of various milestones relating to the development, approval and marketing of MosaiQ and 106,000 MRSUs were outstanding, which will vest if the volume weighted average price of the Company's ordinary shares exceeds \$22 for a continuous 20 day period between April 1, 2019 and December 31, 2019.

The fair value of the Company's ordinary shares was \$9.01 per share on March 31, 2019.

As of March 31, 2019, total compensation cost related to share options and RSUs granted but not yet recognized was \$4,333 net of estimated forfeitures. This cost will be amortized to expense over a weighted average remaining period of 10 months and will be adjusted for subsequent changes in estimated forfeitures.

**Note 10. Income Taxes**

No provision has been made for current income taxes in any period. The statutory standard corporate income tax rate of the Company in Jersey is 0%. The principal operating subsidiaries operate in the United States, the United Kingdom and Switzerland and are subject to corporate income taxes in those countries. All these entities have trading losses available to shelter any taxable profits and accordingly, no current income taxes liabilities have been provided for. In the year ended March 31, 2018, as a result of improvements in the profitability of a subsidiary, the valuation allowances held against the deferred tax assets in that subsidiary, which principally comprised of trading losses, have been reduced resulting in the recognition of deferred tax assets of \$649. Utilization of the trading losses against the profits of the subsidiary in the year ended March 31, 2019, resulted in a reduction in the deferred tax assets of \$44 with a corresponding provision for income taxes of the same amount.

A reconciliation of the income tax expense at the statutory rate to the provision for income taxes is as follows:

	Year ended March 31,		
	2019	2018	2017
Income tax expense at statutory rate	\$ —	\$ —	\$ —
Foreign tax rate differential	5,287	4,841	1,823
(Increase) decrease in valuation allowance against deferred tax assets	(5,331)	(4,192)	(1,823)
Provision for income tax	\$ (44)	\$ 649	\$ —

Significant components of deferred tax assets are as follows:

	March 31, 2019	March 31, 2018
Provisions and reserves	\$ 1,442	\$ 1,327
Fixed assets basis difference	\$ 34	\$ —
Net operating loss carry forwards	17,330	12,476
Gross deferred tax assets	\$ 18,806	\$ 13,803
Fixed assets basis difference	\$ —	\$ (284)
Gross deferred tax liabilities	\$ —	\$ (284)
Net deferred tax asset	\$ 18,806	\$ 13,519
Valuation allowance	(18,201)	(12,870)
Total	\$ 605	\$ 649

The balance sheet classification of net deferred tax assets is as follows:

	March 31, 2019	March 31, 2018
Net noncurrent deferred tax assets	\$ 605	\$ 649
Total	\$ 605	\$ 649

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

As of March 31, 2019, the Company has net operating loss carry forwards of approximately \$195,003 and \$107 of U.S. state net operating losses, which will be available to offset future taxable income. If not used, losses with a tax effect of approximately \$15,911 will expire between 2022 and 2027 and losses with a tax effect of \$380 will expire in 2037. The remaining portion of the carry forward losses arose in jurisdictions where losses do not expire.

The Company recognizes interest and penalties accrued related to unrecognized tax benefits in tax expense. During the fiscal years ended March 31, 2019, March 31, 2018 and March 31, 2017, the Company had no amounts accrued for interest and penalties. The Company does not currently anticipate that the total amount of unrecognized tax benefits will result in material changes to its financial position within the next 12 months.

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

The Company files separate company income tax returns in its domestic and foreign jurisdictions. All necessary income tax filings in all jurisdictions have been completed for all years up to and including March 31, 2018 and there are no ongoing tax examinations in any jurisdiction.

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

#### Note 11. Pension Plans

The Company operates a defined contribution pension scheme. The assets of the scheme are held separately from those of the Company in an independently administered fund. The pension cost charge represents the contribution payable by the Company to the fund during the year. Defined contribution pension costs during the years ended March 31, 2019, 2018 and 2017 amounted to \$750, \$1,197 and \$742, respectively.

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

These circumstances require that the Swiss employee pension arrangements be treated as a defined benefit plan under ASC 715 *Compensation – Retirement Benefits*. Accordingly, an actuarial valuation of the pension obligation has been performed. At March 31, 2019 and 2018, the accumulated pension obligation amounted to \$17,784 and \$15,784, respectively, as compared with plan assets of \$10,416 and \$9,616, respectively. Therefore, the net funded status was an obligation of \$7,368 and \$6,168, as of March 31, 2019 and March 31, 2018 respectively, which were recorded as liabilities on the consolidated balance sheets.

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

	Year ended	
	March 31, 2019	March 31, 2018
Pension benefit obligation, beginning of year	\$ 15,784	\$ 13,318
Service cost	1,574	1,601
Contributions paid by plan participants	1,438	2,627
Interest cost	153	110
Benefits paid	(1,462)	(2,601)
Plan amendment	(100)	—
Actuarial loss	1,097	32
Foreign currency translation	(700)	697
Pension benefit obligation, end of year	\$ 17,784	\$ 15,784

	Year ended	
	March 31, 2019	March 31, 2018
Fair value of plan assets, beginning of year	\$ 9,616	\$ 7,981
Actual return on plan assets	89	78
Contributions paid by employer	1,156	1,110
Contributions paid by plan participants	1,438	2,627
Benefits paid	(1,462)	(2,601)
Foreign currency translation	(421)	421
Fair value of plan assets, end of year	\$ 10,416	\$ 9,616



Contributions paid by plan participants include \$749 and \$1,958 of payments into the scheme on new employees joining in the years ended March 31, 2019 and March 31, 2018, respectively.

	Year ended	
	March 31, 2019	March 31, 2018
Pension benefit obligation, end of year	\$ 17,784	\$ 15,784
Fair value of plan assets, end of year	10,416	9,616
Net funding obligation, end of year	\$ 7,368	\$ 6,168

The assumptions used to determine the pension benefit obligation at the end of each financial year are:

	March 31, 2019	March 31, 2018	March 31, 2017
Price inflation	1.00%	1.00%	1.00%
Discount rate	0.70%	1.00%	0.80%
Expected return on plan assets	1.20%	1.40%	1.40%
Average rate of salary increase	1.00%	1.00%	1.00%

Each employee participating in the plan has an individual portfolio that is managed by Swiss Life under a collective arrangement. Plan assets comprise the surrender value of the portfolio of active insured scheme participants. The expected return on plan assets was determined after consideration of current and historical levels of return and discussions with Swiss Life. The discount rate is based on bond yields at March 31, 2019 and March 31, 2018 on the Swiss bond market over a fifteen to twenty-five year period.

The net pension costs for the year are based on the assumptions adopted at the start of each financial year and comprise:

	Year ended		
	March 31, 2019	March 31, 2018	March 31, 2017
Employer service cost	\$ 1,574	\$ 1,601	\$ 1,353
Interest cost	153	110	39
Expected return on plan assets	(131)	(115)	(61)
Amortization of prior service credit	(14)	(14)	(14)
Amortization of net loss	154	188	186
Net pension cost	\$ 1,736	\$ 1,770	\$ 1,503

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

	Year ended		
	March 31, 2019	March 31, 2018	March 31, 2017
Net actuarial loss	\$ 1,027	\$ 67	\$ 582
Amortization of prior service credit	14	14	14
Amortization of net loss	(154)	(188)	(186)
	\$ 887	\$ (107)	\$ 410

The cumulative amounts recognized in other comprehensive income were \$5,692 and \$4,805 at March 31, 2019 and March 31, 2018 respectively. This represented a net loss of \$5,902 and \$5,029 at March 31, 2019 and March 31, 2018 respectively and a prior service credit of \$210 and \$224 at March 31, 2019 and March 31, 2018 respectively.

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

2020	\$	979
2021	\$	916
2022	\$	861
2023	\$	814
2024	\$	773
2025 to 2030	\$	3,553

Expected annual employer contributions to the plan in the year ending March 31, 2020 amount to \$1,208.

#### Note 12. Net Loss Per Share

In accordance with ASC 260 *Earnings Per Share*, basic earnings available to ordinary shareholders per share is computed based on the weighted average number of ordinary shares outstanding during each period. Diluted earnings available to ordinary shareholders per share is computed based on the weighted average number of ordinary shares outstanding during each period, plus potential ordinary shares considered outstanding during the period, as long as the inclusion of such shares is not anti-dilutive. Potential ordinary shares consist of the incremental ordinary shares issuable upon the exercise of share options (using the treasury shares method), RSUs (including MRSUs) and warrants to acquire ordinary shares.

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

	Year ended March 31,		
	2019	2018	2017
<b>Numerator:</b>			
Net loss	\$ (105,386)	\$ (82,338)	\$ (85,069)
Net loss available to ordinary shareholders - basic and diluted	\$ (105,386)	\$ (82,338)	\$ (85,069)
<b>Denominator:</b>			
Weighted-average shares outstanding - basic and diluted	54,874,391	40,839,309	28,145,472
Loss per share - basic and diluted	\$ (1.92)	\$ (2.02)	\$ (3.02)

The following sets out the numbers of the options, RSUs (including MRSUs) and warrants to purchase ordinary shares excluded from the above computation of earnings per share for the years ended March 31, 2019, March 31, 2018 and March 31, 2017, as their inclusion would have been anti-dilutive.

	<u>March 31,</u> <u>2019</u>	<u>March 31,</u> <u>2018</u>	<u>March 31,</u> <u>2017</u>
Ordinary shares issuable on exercise of options to purchase ordinary shares	1,936,397	2,096,283	1,948,917
Restricted share units awarded, including the multi-year performance related restricted share units	966,689	773,379	843,608
Ordinary shares issuable on exercise of warrants at \$16.14 per share	111,525	111,525	111,525
Ordinary shares issuable on exercise of warrants at \$9.375 per share	64,000	64,000	64,000
Ordinary shares issuable on exercise of warrants at \$5.80 per share	—	8,414,683	—
Ordinary shares issuable on exercise of warrants at \$0.01 per share	—	550,000	—
	<u>3,078,611</u>	<u>12,009,870</u>	<u>2,968,050</u>

**Note 13. Subsequent Events**

On April 30, 2019, the Company was notified that the CE Mark of its initial MosaiQ IH Microarray had been granted. On May 15, 2019, the CE Marking Notes were issued. The Company received \$24.1 million of net proceeds after paying debt issue expenses and deposited \$1.5 million into the cash reserve account under the terms of the indenture.

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

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

**Item 9A. Controls and procedures****(a) Evaluation of disclosure controls and procedures**

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have conducted an evaluation of our disclosure controls and procedures, as that term is defined in Rule 13a-15(e) of the Exchange Act, as of March 31, 2019. Based on such evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of March 31, 2019 to ensure that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms, and is accumulated and communicated to our management, including our Chief Executive and Chief Financial Officers, or persons performing similar functions, as appropriate to allow timely decisions regarding required disclosure.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Our internal control system was designed to provide reasonable assurance to our management and our directors regarding the preparation and presentation of our published financial statements.

Management assessed the effectiveness of our internal control over financial reporting as of March 31, 2019. In making this assessment, it used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control – Integrated Framework (2013). Because of its inherent limitations, a system of internal control over financial reporting can provide only reasonable assurance and may not prevent or detect misstatements. Management regularly monitors our internal control over financial reporting, and actions are taken to correct any deficiencies as they are identified. Based on its assessment, management has concluded that our internal control over financial reporting was effective as of March 31, 2019.

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

**(c) Changes in internal control over financial reporting**

Other than disclosed below, there were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of the year ended March 31, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

**(d) Remediation of Previously Reported Material Weakness**

As previously disclosed under "Item 9A. Controls and Procedures" in our Annual Report on Form 10-K for the year ended March 31, 2018, management identified a material weakness in the design of our internal control over the deferred income tax accounting for complex, non-routine transactions. A material weakness is a control deficiency (within the meaning of Public Company Accounting Oversight Board Auditing Standard No. 2), or combination of control deficiencies, that results in more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by employees in the normal course of their work.

Management concluded at March 31, 2018 that we did not have adequate supervision and review controls over the advice provided by third party tax advisers, including the accounting for the related deferred income taxes. This material weakness resulted in a misstatement which was corrected by post-close adjustments to deferred tax prior to the issuance of the consolidated financial statements for the year ended March 31, 2018. As a result, management concluded that, as of March 31, 2018, we did not maintain effective internal control over financial reporting based on the criteria established in *Internal Control-Integrated Framework 2013* issued by COSO.

During the fiscal year ended March 31, 2019, we remediated the material weakness in our internal control over financial reporting described above. In order to remediate the material weakness, we obtained further tax advice on the transaction that resulted in the material weakness being identified at March 31, 2018 and we introduced specific management review control procedures related to the provision of tax advice and the related accounting treatment under US GAAP of complex non-routine transactions.

Given the remedial measures, testing of applicable controls and the determination that controls are designed and operating effectively, management has concluded that the material weakness previously identified has been remediated as of March 31, 2019.

**Item 9B. Other information**

None.

**PART III**

**Item 10. Directors, Executive Officers and Corporate Governance**

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 31, 2019.

**Item 11. Executive Compensation**

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 31, 2019.

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

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 31, 2019.

**Item 13. Certain Relationships and Related Transactions and Director Independence**

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 31, 2019.

**Item 14. Principal Accounting Fees and Services**

The information required by this item is incorporated herein by reference to our definitive proxy statement, which will be filed not later than July 31, 2019.

PART IV

Item 15. Exhibits, Financial Statement Schedules

1. Financial Statements

Our consolidated financial statements, together with the independent registered public accounting firm's report thereon, are set forth on pages 64 through 89 of this annual report on Form 10-K and are incorporated herein by reference. See Item 8, "Financial Statements and Supplementary Data," filed herewith, for a list of financial statements.

2. Financial Statement Schedules

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

3. Exhibit Index

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

Exhibit number	Description of exhibit
3.1	<a href="#">Amended Articles of Association (Filed as Exhibit 3.1 to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)</a>
4.1	<a href="#">Form of Ordinary Shares Certificate (Filed as Exhibit 4.1 to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)</a>
4.2	<a href="#">Warrant to Purchase C Preference Shares, dated December 26, 2013, issued to Midcap Funding V, LLC (Filed as Exhibit 4.2 to our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)</a>
4.3	<a href="#">Registration Rights Agreement, dated November 25, 2014, by and among Quotient Limited and the Subscribers named therein (Filed as Exhibit 4.2 to our Current Report on Form 8-K on November 26, 2014 and incorporated herein by reference)</a>
4.4	<a href="#">Statement of Rights in relation to Preference Shares in the capital of Quotient Limited (Filed as Exhibit 4.1 to our Current Report on Form 8-K on January 29, 2015 and incorporated herein by reference)</a>
4.5	<a href="#">Warrant to Purchase 66,915 Ordinary Shares, dated September 25, 2015, issued to Midcap Financial Trust (filed as Exhibit 4.1 to our Current Report on Form 8-K on October 1, 2015 and incorporated herein by reference)</a>
4.6	<a href="#">Warrant to Purchase 26,023 Ordinary Shares, dated September 25, 2015, issued to Oxford Finance LLC (filed as Exhibit 4.2 to our Current Report on Form 8-K on October 1, 2015 and incorporated herein by reference)</a>
4.7	<a href="#">Warrant to Purchase 14,126 Ordinary Shares, dated September 25, 2015, issued to Oxford Finance LLC (filed as Exhibit 4.3 to our Current Report on Form 8-K on October 1, 2015 and incorporated herein by reference)</a>
4.8	<a href="#">Warrant to Purchase 4,461 Ordinary Shares, dated September 25, 2015, issued to Flexpoint MCLS SPV LLC (filed as Exhibit 4.4 to our Current Report on Form 8-K on October 1, 2015 and incorporated herein by reference)</a>
4.9	<a href="#">Indenture, dated as of October 14, 2016, among the Company, the Guarantors from time to time party thereto and U.S. Bank National Association, as trustee and collateral agent (filed as exhibit 4.1 to our report on Form 8-K filed on October 14, 2016 and incorporated herein by reference)</a>
4.10	<a href="#">Registration Rights Agreement, dated October 24, 2017, by and among Quotient Limited and the Subscribers named therein (Filed as Exhibit 4.1 of our Current Report on 8-K on October 25, 2017 and incorporated herein by reference)</a>
4.11	<a href="#">First Supplemental Indenture, dated as of December 4, 2018, among Quotient Limited, the Guarantors from time to time party thereto and U.S. Bank National Association, as trustees and collateral agent (filed as exhibit 4.1 to our Form 8-K filed on December 5, 2018 and incorporated herein by reference)</a>
10.1	<a href="#">Employment Agreement, dated March 9, 2009, between Alba Bioscience Limited and Jeremy Stackawitz (Filed as Exhibit 10.3 to our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)</a>
10.2	<a href="#">Service Agreement, dated November 21, 2012, between Quotient Biodiagnostics Holding Limited (since renamed Quotient Limited) and Edward Farrell (Filed as Exhibit 10.4 to our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)</a>

Exhibit number	Description of exhibit
10.3	<a href="#">Service Agreement, dated August 14, 2012, between Quotient Biodiagnostics Holdings Limited (since renamed Quotient Limited) and Roland Boyd (Filed as Exhibit 10.5 to our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)</a>
10.4	<a href="#">Employment agreement, dated February 9, 2017, between Quotient Limited and Christopher Lindop (Filed as Exhibit 10.2 to our Current Report on Form 8-K on February, 14 2017 and incorporated herein by reference)</a>
10.5	<a href="#">Amendment to employment agreement between Quotient Limited and Christopher Lindop dated April 5, 2018 (Filed as Exhibit 10.1 to our Quarterly Report on Form 10-Q on August 7, 2018 and incorporated herein by reference)</a>
10.6	<a href="#">Amendment to employment agreement between Quotient Limited and Christopher Lindop, dated as of September 19, 2018, (Filed as Exhibit 10.3 to our Quarterly Report on Form 10-Q on November 6, 2018 and incorporated herein by reference)</a>
10.7	<a href="#">Eysins, Switzerland Lease Agreement, dated March 10, 2010, between Nemaco Fléchères B.V. and Quotient Suisse SA (Filed as Exhibit 10.12 to our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)</a>
10.8	<a href="#">Eysins, Switzerland, Lease Assignment Agreement, dated December 9, 2013, by and among Fidfund Management SA, Mondelez Europe GmbH, Quotient Suisse SA and Quotient Limited, (Filed as Exhibit 10.13 to our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)</a>
10.9	<a href="#">Form of Indemnification Agreement (Filed as Exhibit 10.16 to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)</a>
10.10	<a href="#">2012 Option Plan (Filed as Exhibit 10.17 to our Registration Statement on Form S-1 (File No. 333-194390) on March 7, 2014 and incorporated herein by reference)</a>
10.11	<a href="#">Quotient Limited 2014 Stock Incentive Plan (as adopted on March 31, 2014 and amended and restated on October 28, 2016 and further amended and restated on October 31, 2018) (incorporated by reference to Exhibit A to Amendment No. 1 to the Definitive Proxy Statement on Schedule 14A filed with the Securities and Exchange Commission on August 31, 2018)</a>
10.12†	<a href="#">TTP Intellectual Property Rights Agreement, dated March 4, 2014, between The Technology Partnership plc and QBD (OS-IP) Limited, (Filed as Exhibit 10.20 to Amendment No. 2 to our Registration Statement on Form S-1 (File No. 333-194390) on April 3, 2014 and incorporated herein by reference)</a>
10.13†	<a href="#">STRATEC Supply and Manufacturing Agreement, dated April 1, 2014, between STRATEC Biomedical AG and QBD (OS-IP) Limited, (Filed as Exhibit 10.22 to Amendment No. 3 to our Registration Statement on Form S-1 (File No. 333-194390) on April 7, 2014 and incorporated herein by reference)</a>
10.14	<a href="#">Form of Restricted Stock Unit Award Agreement (Filed as Exhibit 10.24 to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)</a>
10.15	<a href="#">Form of Restricted Stock Award Agreement (Filed as Exhibit 10.25 to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)</a>
10.16	<a href="#">Form of Option Award Agreement (Filed as Exhibit 10.26 to Amendment No. 4 to our Registration Statement on Form S-1 (File No. 333-194390) on April 14, 2014 and incorporated herein by reference)</a>
10.17	<a href="#">Form of Letter of Appointment for a Non-Executive Director (Filed as Exhibit 10.27 to Amendment No. 5 to our Registration Statement on Form S-1 (File No. 333-194390) on April 15, 2014 and incorporated herein by reference)</a>
10.18	<a href="#">Subscription Agreement, dated November 25, 2014, by and among Quotient Limited and the Subscribers named therein, (Filed as Exhibit 10.2 to our Current Report on Form 8-K on November 26, 2014 and incorporated herein by reference)</a>
10.19	<a href="#">Subscription Agreement, dated January 29, 2015, between Quotient Limited and Ortho-Clinical Diagnostics Finco S.Á.R.L, (Filed as Exhibit 10.1 to our Current Report on Form 8-K on January 29, 2015 and incorporated herein by reference)</a>
10.20†	<a href="#">Distribution and Supply Agreement, dated January 29, 2015, between QBD (OS IP) Limited, Quotient Suisse SA and Ortho-Clinical Diagnostics, Inc. (Filed as Exhibit 10.34 to our Annual Report on Form 10-K on June 1, 2015 and incorporated herein by reference)</a>
10.21†	<a href="#">First Amendment to TTP Intellectual Property Rights Agreement, dated March 28, 2016, between The Technology Partnership plc and QBD (OS-IP) Limited (filed as Exhibit 10.38 to our Annual Report on Form 10-K on May 31, 2016 and incorporated herein by reference)</a>
10.22	<a href="#">Form of Purchase Agreement, dated as of October 14, 2016 (filed as exhibit 10.1 to our report on Form 8-K filed on October 14, 2016 and incorporated herein by reference)</a>
10.23	<a href="#">Form of Royalty Rights Agreement, dated as of October 14, 2016 (filed as exhibit 10.2 to our report on Form 8-K filed on October 14, 2016 and incorporated herein by reference)</a>



Exhibit number	Description of exhibit
10.24	<a href="#">Collateral Agreement, dated as of October 14, 2016, among the Company the Subsidiary Parties from time to time party thereto and U.S. Bank National Association, as trustee and collateral agent (filed as exhibit 10.3 to our report on Form 8-K filed on October 14, 2016 and incorporated herein by reference)</a>
10.25	<a href="#">Subscription Agreement dated February 9, 2017 between Quotient Limited and Christopher J. Lindop (filed as Exhibit 10.1 to our Current Report on Form 8-K on February, 14 2017 and incorporated herein by reference)</a>
10.26	<a href="#">Form of Change of Control Agreement dated as of August 7, 2017 between the Company and the following executive officers: Christopher Lindop, Edward Farrell, Jeremy Stackawitz and Roland Boyd (filed as Exhibit 10.1 to our report on Form 8-K filed on August 10, 2017 and incorporated herein by reference)</a>
10.27	<a href="#">Form of Subscription Agreement, dated October 24, 2017 by an among Quotient Limited and the Subscribers named therein (filed as Exhibit 10.1 to our report on Form 8-K filed on October 25, 2017 and incorporated herein by reference)</a>
10.28	<a href="#">Lease Agreement, dated July 14, 2017, by and between Quotient Biocampus Limited and Alba Bioscience Limited (filed as Exhibit 10.1 to our report on Form 8-K filed on March 26, 2018 and incorporated herein by reference)</a>
10.29	<a href="#">Minute of Variation of Lease, dated March 23, 2018, by and between Quotient Biocampus Limited and Alba Bioscience Limited (filed as Exhibit 10.2 to our report on Form 8-K filed on March 26, 2018 and incorporated herein by reference)</a>
10.30	<a href="#">Guarantee Agreement, dated March 23, 2018, by Quotient Limited and Quotient Suisse SA in favor of Roslin Assets Limited (filed as Exhibit 10.3 to our report on Form 8-K filed on March 26, 2018 and incorporated herein by reference)</a>
10.31	<a href="#">Disposition Agreement, dated March 23, 2018, by Quotient Biocampus Limited in favor of Roslin Assets Limited (filed as Exhibit 10.4 to our report on Form 8-K filed on March 26, 2018 and incorporated herein by reference)</a>
10.32	<a href="#">Rent Deposit Agreement, dated March 23, 2018, by and between Alba Bioscience Limited and Roslin Assets Limited (filed as Exhibit 10.5 to our report on Form 8-K filed on March 26, 2018 and incorporated herein by reference)</a>
10.33	<a href="#">Principal Offer, dated February 20, 2018, by Quotient Biocampus Limited and Roslin Assets Limited (filed as Exhibit 10.45 to our Annual Report on form 10-K filed on May 30, 2018 and incorporated herein by reference)</a>
10.34	<a href="#">Part Time Employment Agreement, dated as of April, 2018, by and between Quotient Limited and Franz Walt (filed as Exhibit 10.1 to our report on Form 8-K filed on April 5, 2018 and incorporated herein by reference)</a>
10.35	<a href="#">Separation Agreement, dated as of May 7, 2018, by and among Quotient Limited, D. J. Paul Cowan and Deidre Cowan (filed as Exhibit 10.1 to our report on Form 8-K filed May 11, 2018 and incorporated herein by reference)</a>
10.36	<a href="#">Form of Royalty Right Agreement dated as of June 29, 2018 (filed as exhibit 10.1 to our Form 8-K filed on June 29, 2018 and incorporated herein by reference)</a>
10.37	<a href="#">Form of Amendment to Royalty Right Agreement, dated as of June 29, 2018 (filed as exhibit 10.3 to our Quarterly Report on Form 10-Q on August 7, 2018)</a>
10.38	<a href="#">Subscription agreement dated as of August 3, 2018 by and between Quotient Limited and Franz Walt (filed as exhibit 10.1 to our Form 8-K filed on August 8, 2018 and incorporated herein by reference)</a>
10.39	<a href="#">Subscription agreement dated as of August 3, 2018 by and between Quotient Limited and Heino von Prondzynski (filed as exhibit 10.2 to our Form 8-K filed on August 8, 2018 and incorporated herein by reference)</a>
10.40	<a href="#">Supply Agreement between Alba Bioscience Limited and Ortho-Clinical Diagnostics, Inc. entered into on December 17, 2018 (filed as exhibit 10.2 to our Quarterly Report on Form 10-O filed on February 2, 2019 and incorporated herein by reference)</a>
10.41	<a href="#">Form of Royalty Right Agreements, dated as of December 18, 2018 (filed as exhibit 10.1 to our Form 8-K filed on December 5, 2018 and incorporated herein by reference)</a>
10.42	<a href="#">Form of Purchase Agreement, dated as of January 15, 2019 (filed as exhibit 10.1 to our report on Form 8-K filed on January 16, 2019 and incorporated herein by reference)</a>
10.43†	<a href="#">Second Amendment to TTP Intellectual Property Rights Agreement, dated as of April 24, 2017, between The Technology Partnership plc and QBD (OS-IP) Limited (filed as exhibit 99.2 to our Form 8-K filed on December 5, 2018 and incorporated herein by reference)</a>

Exhibit number	Description of exhibit
10.44†	<a href="#">First Amendment to STRATEC Supply and Manufacturing Agreement, dated as of December 19, 2016, between STRATEC Biomedical AG and OBD (QS IP) Limited (filed as exhibit 99.3 to our Form 8-K filed on December 5, 2018 and incorporated herein by reference)</a>
21.1*	<a href="#">List of Subsidiaries</a>
23.1*	<a href="#">Consent of Ernst &amp; Young LLP</a>
31.1*	<a href="#">Certification of the Principal Executive Officer pursuant Section 302 of the Sarbanes-Oxley Act of 2002</a>
31.2*	<a href="#">Certification of the Principal Financial Officer pursuant Section 302 of the Sarbanes-Oxley Act of 2002</a>
32.1*	<a href="#">Certification of the Principal Executive Officer pursuant Section 906 of the Sarbanes-Oxley Act of 2002</a>
32.2*	<a href="#">Certification of the Principal Financial Officer pursuant Section 906 of the Sarbanes-Oxley Act of 2002</a>
101#	The following financial statements from the Company's Annual Report on Form 10-K for the year ended March 31, 2019, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of March 31, 2019 and 2018, (ii) Consolidated Statements of Comprehensive Loss for the years ended March 31, 2019, 2018 and 2017, (iii) Consolidated Statements of Redeemable Convertible Preference Shares and Changes in Shareholders' Equity for the years ended March 31, 2019, 2018 and 2017, (iv) Consolidated Statements of Cash Flows for the years ended March 31, 2019, 2018 and 2017 and (v) Notes to Consolidated Financial Statements, tagged as blocks of text and including detailed tags.

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

\* Filed herewith.

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

**Item 16. Form 10-K Summary**

None.

### Signatures

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, in Eysins, Switzerland on May 29, 2019

#### QUOTIENT LIMITED

By: /s/ Franz Walt  
Franz Walt  
Chief Executive Officer

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

<u>Signature</u>	<u>Title</u>	<u>Date</u>
<u>/s/ Franz Walt</u> Franz Walt	Chief Executive Officer (Principal Executive Officer)	May 29, 2019
<u>/s/ Christopher Lindop</u> Christopher Lindop	Chief Financial Officer (Principal Financial Officer)	May 29, 2019
<u>/s/ Roland Boyd</u> Roland Boyd	Group Financial Controller and Treasurer (Principal Accounting Officer)	May 29, 2019
<u>/s/ Heino von Prondzynski</u> Heino von Prondzynski	Chairman of the Board of Directors	May 29, 2019
<u>/s/ Thomas Bologna</u> Thomas Bologna	Director	May 29, 2019
<u>/s/ Frederick Hallsworth</u> Frederick Hallsworth	Director	May 29, 2019
<u>/s/ Brian McDonough</u> Brian McDonough	Director	May 29, 2019
<u>/s/ Sarah O'Connor</u> Sarah O'Connor	Director	May 29, 2019
<u>/s/ Zubeen Shroff</u> Zubeen Shroff	Director	May 29, 2019
<u>/s/ John Wilkerson</u> John Wilkerson	Director	May 29, 2019
<u>/s/ Jeremy Stackawitz</u> Jeremy Stackawitz	Authorized Representative in the United States	May 29, 2019

List of Subsidiaries of Quotient Limited

<b>Name</b>	<b>Place of Incorporation</b>
QBD (QS IP) Limited	Jersey, Channel Islands
Quotient Biodiagnostics, Inc.	Delaware, USA
Alba Bioscience Limited	Scotland
Quotient Suisse SA	Switzerland
Quotient Biocampus Limited	Scotland

## Consent of Independent Registered Public Accounting Firm

We consent to (i) the incorporation by reference in the following Registration Statements of our report dated May 29, 2019, with respect to the consolidated financial statements of Quotient Limited included in this Annual Report on Form 10-K for the year ended March 31, 2019 and (ii) the reference to our firm under the heading "Experts" in the related Prospectuses and Prospectus Supplements:

1. the Registration Statement on Form S-8 (File No. 333-228330) pertaining to the registration of 550,000 shares authorized for issuance under the Second Amended and Restated 2014 Plan of Quotient Limited;
2. the Registration Statement on Form S-3 (File No. 333-226800) pertaining to the registration of up to \$200,000,000 Ordinary Shares, Preference Shares, Debt Securities, Rights to Purchase Ordinary Shares, Rights to Purchase Preference Shares, Warrants to Purchase Ordinary Shares, Warrants to Purchase Preference Shares and Warrants to Purchase Debt Securities;
3. the Registration Statement on Form S-8 (File No. 333-225553) pertaining to the registration of 200,000 shares authorized for issuance under the Amended and Restated 2014 Stock Incentive Plan (now referred to as the Second Amended and Restated 2014 Plan) of Quotient Limited;
4. the Registration Statement on Form S-3 (File No. 333-221470) pertaining to the registration of up to 16,829,366 Ordinary Shares and up to 8,414,683 new warrants;
5. the Registration Statement on Form S-8 (File No. 333-218462) pertaining to the registration of 200,000 shares authorized for issuance under the Amended and Restated 2014 Stock Incentive Plan (now referred to as the Second Amended and Restated 2014 Plan) of Quotient Limited;
6. the Registration Statement on Form S-3 (File No. 333-203818) pertaining to the registration for resale of 1,939,614 Ordinary Shares issued and outstanding and 850,000 Ordinary Shares issuable upon exercise of a Pre-funded Warrant;
7. the Registration Statement on Form S-8 (File No. 333-195507) pertaining to the registration of 779,462 shares issuable upon exercise of outstanding options granted under the 2013 Enterprise Management Plan (now referred to as the 2012 Option Plan) and 1,500,000 shares reserved for issuance under the 2014 Stock Incentive Plan (now referred to as the Second Amended and Restated 2014 Plan) of Quotient Limited.
8. the Registration Statement on Form S-8 (File No. 333-214483) pertaining to the registration of 1,120,205 shares reserved for issuance under the 2014 Stock Incentive Plan (now referred to as the Second Amended and Restated 2014 Plan) of Quotient Limited;

/s/ Ernst & Young LLP

Belfast, United Kingdom  
May 29, 2019

## CERTIFICATION

I, Franz Walt, certify that:

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

Date: May 29, 2019

/s/ Franz Walt  
\_\_\_\_\_  
Franz Walt  
Chief Executive Officer

## CERTIFICATION

I, Christopher Lindop, certify that:

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

Date: May 29, 2019

/s/ Christopher Lindop  
Christopher Lindop  
Chief Financial Officer



**CERTIFICATION**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Quotient Limited, a company incorporated under the laws of Jersey, Channel Islands (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K of the Company for the year ended March 31, 2019 (the "Form 10-K") filed with the Securities and Exchange Commission on the date hereof fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 29, 2019

/s/ Franz Walt

Franz Walt

*Chief Executive Officer*

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

**CERTIFICATION**

Pursuant to section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of section 1350, chapter 63 of title 18, United States Code), the undersigned officer of Quotient Limited, a company incorporated under the laws of Jersey, Channel Islands (the "Company"), does hereby certify, to such officer's knowledge, that:

The Annual Report on Form 10-K of the Company for the year ended March 31, 2019 (the "Form 10-K") filed with the Securities and Exchange Commission on the date hereof fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, and the information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 29, 2019

/s/ Christopher Lindop  
Christopher Lindop  
*Chief Financial Officer*

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