# QUOTIENT LTD

## FORM 8-K
(Current report filing)

Filed 08/07/17 for the Period Ending 08/07/17

| | |
|---|---|
| Telephone | 41274832286 |
| CIK | 0001596946 |
| Symbol | QTNT |
| SIC Code | 2835 - In Vitro and In Vivo Diagnostic Substances |
| Industry | Medical Equipment, Supplies & Distribution |
| Sector | Healthcare |
| Fiscal Year | 03/31 |

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

---

# FORM 8-K

---

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): August 7, 2017 (August 7, 2017)**

---

# QUOTIENT LIMITED
**(Exact name of registrant as specified in its charter)**

| **Jersey, Channel Islands** | **001-36415** | **Not Applicable** |
|---|---|---|
| **(State or other jurisdiction of incorporation)** | **(Commission File Number)** | **(IRS Employer Identification No.)** |

| | |
|---|---|
| **Pentlands Science Park<br>Bush Loan, Penicuik, Midlothian<br>EH26 OPZ, United Kingdom** | **Not Applicable** |
| **(Address of principal executive offices)** | **(Zip Code)** |

**Registrant's telephone number, including area code: 011-44-131-445-6159**

**n/a**
**(Former name or former address, if changed since last report.)**

---

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☒

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

**Item 2.02. Results of Operatio ns and Financial Condition.**

On August 7, 2017, Quotient Limited issued an earnings release announcing its financial results for the quarter ended June 30, 2017. A copy of the earnings release is attached as Exhibit 99.1 hereto and incorporated herein by reference.

The information in this Current Report, including the exhibit hereto, is being furnished and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that Section. The information in this Current Report shall not be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, unless it is specifically incorporated by reference therein.

**Item 9.01. Financial Statements and Exhibits.**

Exhibit 99.1 Earnings Release, dated August 7, 2017.

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

**QUOTIENT LIMITED**

By: /s/ Paul Cowan
Name: Paul Cowan
Title: Chief Executive Officer

Date: August 7, 2017

## INDEX TO EXHIBITS

| Exhibit number | Description of exhibit |
|---|---|
| 99.1 | Earnings Release, dated August 7, 2017 . |

**Exhibit 99.1**

# Quotient Limited Reports Results From Ongoing MosaiQ Performance Evaluation Studies and First Quarter Fiscal 2018 Financial Results

- ***Latest performance evaluation studies confirm substantial concordance with predicate technologies for blood grouping and initial diseases screening applications***
- ***European field trials expected to be completed in CY17***
- ***Record reagent revenues recorded during the quarter, exceeding guidance***
- ***Six new reagent products licensed by the FDA for sale in the U.S.***

**JERSEY, Channel Islands, August 7, 2017 (GLOBENEWSWIRE)** -- Quotient Limited (NASDAQ:QTNT), a commercial-stage diagnostics company, today reported progress on performance evaluation studies for MosaiQ™ and financial results for its fiscal first quarter ended June 30, 2017.

“We are continuing to make progress towards our goal of obtaining an initial CE mark for MosaiQ. The key step in this process, which we are providing an update on today, involves using market ready MosaiQ instruments as well as blood grouping and disease screening microarrays manufactured in our validated manufacturing facility to test for concordance with blood samples supplied and previously characterized by independent blood collection agencies. These results represent a major technical achievement for the project and give us added confidence of being field trial ready in the near future.” said Paul Cowan, Chairman and Chief Executive Officer of Quotient. Mr. Cowan added “The value that MosaiQ will deliver for our potential customers was underscored during our recent participation at ISBT’s annual meeting held in Copenhagen this June. More than 230 ISBT delegates joined us at a symposium to discuss the benefits associated with routine comprehensive antigen typing for donated blood products, which MosaiQ will make possible on a routine basis once it is available in the market.”

**MosaiQ Platform**

MosaiQ, Quotient's next-generation platform delivers fast, comprehensive antigen typing, antibody detection and disease screening results, using a single low volume sample in a high throughput automated format. MosaiQ represents a transformative and highly disruptive unified testing platform for transfusion diagnostics. Feasibility has also been demonstrated with respect to the detection of nucleic acids (DNA or RNA) using the MosaiQ platform. Through MosaiQ, Quotient expects to deliver substantial value to donor testing laboratories worldwide by providing affordable, routine comprehensive characterization and screening of blood products, on a single automated instrument platform designed to radically reduce labor costs and complexity associated with existing practice.

**Assay Performance**

Assay performance in the ongoing performance evaluation studies for the MosaiQ IH Microarray (the initial blood grouping microarray) and the MosaiQ SDS Microarray (the initial disease screening microarray) demonstrate substantial concordance compared with predicate technologies. The performance evaluation data were derived using microarrays manufactured in Quotient's validated, high-volume manufacturing facility and run on field trial-ready instruments. The Company has taken the opportunity over the past two months to further improve the performance of the antibody detection assay, and that work is now complete. Final internal verification and validation studies for the MosaiQ IH Microarray and MosaiQ SDS Microarray are the next step in preparation for European field trials later this year. Verification and validation studies are designed to mimic the subsequent field trials.

*MosaiQ IH Microarray - Antigen Typing*

A summary of the most recent performance evaluation data derived in our ongoing study for antigen typing is set out below:

| Blood Group Antigen | A | B | D | C | c | E | e | Cw | K | k |
|---|---|---|---|---|---|---|---|---|---|---|
| Concordance | 100% | 100% | 99.2% | 100% | 96.3% | 100% | 99.3% | 100% | 100% | 100% |

In this study 268 donor samples were tested.

Actions to improve concordance for the c antigen are underway, including modification of the concentration of the detection reagent formulation for this specificity.

*MosaiQ IH Microarray - Antibody Detection*

The most recent performance evaluation study for the antibody detection assay achieved 97% concordance compared with the predicate technology. In this study, 413 donor samples and 50 known positive samples were tested.

*MosaiQ SDS Microarray*

The most recent performance evaluation study for the MosaiQ SDS Microarray achieved 97% sensitivity and 100% specificity for CMV and 98% sensitivity and 100% specificity for syphilis. In this study, 314 donor samples and 88 known positive samples were tested. Known positive samples were selected to test the limits of detection for MosaiQ, hence the achieved sensitivity of 97-98% for both assays. These results indicate that the performance of the MosaiQ SDS Microarray meets or exceeds the established performance characteristics of the predicate technology.

The most recent performance evaluation data for the MosaiQ IH Microarray and MosaiQ SDS Microarray provide confidence in the ultimate outcome of the upcoming verification and validation studies for the se products and ultimately the European field trial s that we expect to complete later this year.

**Regulatory and Commercial Milestones - Next Twelve Months**

- **European Field Trials** – Quotient expects to complete European field trials during CY17
- **European Regulatory Approval** – Upon the successful completion of European field trials Quotient expects to file promptly for European regulatory approval for MosaiQ
- **European Commercialization** – Quotient has commenced the commercialization of MosaiQ in Europe, where it has already received invitations to participate in tenders to be awarded in the middle of CY18
- **U.S. Field Trials** and subsequent **Regulatory Filing** will follow the successful completion of European field trials.

**Fiscal First Quarter 2018 Financial Results**

"The conventional reagent business recognized record product sales in the first quarter, while also having six new reagent products licensed for sale in the U.S. by the FDA," said Paul Cowan. "Strong top line performance was driven by 17% growth in sales to OEM customers, while U.S. direct sales which grew only 2%, were adversely impacted by the expected timing of shipments. Our continued focus on growing these more profitable revenue lines has shown positive results, with significant gross margin improvement in the quarter. Milestone payments earned from the approval for sale in the U.S. of certain rare antisera reagents developed for a key OEM customer contributed $600,000 of other revenues this quarter."

Key revenue and profit results are summarized below (expressed in thousands):

| | Quarter Ended June 30, | |
|---|---|---|
| | **2017** | **2016** |
| **Revenue:** | | |
| Product sales —OEM Customers | $ 4,561 | $ 3,911 |
| Product sales — direct customers and distributors | 1,665 | 1,806 |
| Other revenues | 600 | — |
| **Total revenue** | **$ 6,826** | **$ 5,717** |
| | | |
| Product sales from standing orders (%) | 79% | 76% |
| | | |
| **Gross profit** | **$ 3,994** | **$ 2,626** |
| Gross profit as a % of total revenue | 58.5% | 45.9% |
| Gross margin on product sales (%) | 54.5% | 45.9% |
| **Operating (loss)** | **$ (16,906)** | **$ (16,378)** |

Capital expenditures totaled $5.4 million in 1QFY18 , compared with $6 . 6 million in 1QFY17 , largely reflecting ongoing investment related to the construction of our new conventional reagent manufacturing facility near Edinburgh, Scotland.

Quotient ended 1QFY18 with $40.7 million in cash and other short-term investments and $77.1 million of term debt, net of $5.0 million in an offsetting long-term cash reserve account. On April 10, 2017, the Company completed a public offering of its ordinary shares raising $45.2 million, net of expenses.

**Outlook for the Fiscal Year Ending March 31, 2018**

- Total revenue is still expected to be in the range of $33 to $34 million, including other revenue (product development fees) of approximately $12 million. Forecasted other revenue assumes the receipt of milestone payments contingent upon achievement of regulatory approval for certain products under development. The receipt of these milestone payments involves risks and uncertainties.
- Product sales are still expected to be in the range of $21 to $22 million.
- Operating loss is still expected to be in the range of $63 to $68 million.
- Capital expenditures are still expected to be in the range of $25 to $30 million

Product sales in the second quarter of fiscal 2018 are expected to be in the range of $5.2 to $5.5 million, compared with $4.8 million for the second quarter of fiscal 2017.

Quarterly product sales can fluctuate depending upon the shipment cycles for red blood cell based products, which account for approximately two-thirds of current product sales. These products typically experience 13 shipment cycles per year, equating to three shipments of each product per quarter, except for one quarter per year when four shipments occur. The timing of shipment of bulk antisera products to OEM customers may also move revenues from quarter to quarter. Some seasonality in demand is also experienced around holiday periods in both Europe and the United States. As a result of these factors, Quotient expects to continue to see seasonality and quarter-to-quarter variations in product sales. The timing of product development fees included in other revenues is mostly dependent upon the achievement of pre-negotiated project milestones.

**Conference Call**

Quotient will host a conference call on Tuesday, August 8 th at 8:30 a.m. Eastern Time to discuss its first quarter fiscal 2018 financial results. Participants may access the call by dialing 1-877-407-0784 in the U.S. or 1-201-689-8560 outside the U.S. The conference call will be webcast live on the Company’s website at www.quotientbd.com.

A replay of this conference call will be available through August 30 th by dialing 1-844-512-2921 in the U.S. or 1-412-317-6671 outside the U.S. The replay access code is 13667029.

**About Quotient Limited**

Quotient is a commercial-stage diagnostics company committed to reducing healthcare costs and improving patient care through the provision of innovative tests within established markets. With an initial focus on blood grouping and serological disease screening, Quotient is developing its proprietary MosaiQ ™ technology platform to offer a breadth of tests that is unmatched by existing commercially available transfusion diagnostic instrument platforms. The Company's operations are based in Edinburgh, Scotland; Eysins, Switzerland and Newtown, Pennsylvania.

**Forward-Looking Statements**

*This news release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These forward-looking statements may include statements regarding our expectations of continued growth, the development, regulatory approval, commercialization and impact of MosaiQ ™ and other new products, current estimates of second quarter and full year fiscal 2018 operating results and expectations regarding our future funding sources. Such statements are based on current assumptions that involve risks and uncertainties that could cause actual outcomes and results to differ materially. These risks and uncertainties, many of which are beyond our control, include delays or denials of regulatory approvals or clearances for products or applications; market acceptance of our products; the impact of competition; the impact of facility expansions and expanded product development, clinical, sales and marketing activities on operating expenses; delays or other unforeseen problems with respect to manufacturing, product development or field trial studies; adverse results in connection with any ongoing or future legal proceeding; continued or worsening adverse conditions in the general domestic and global economic markets; as well as the other risks set forth in the Company's filings with the Securities and Exchange Commission. Investors are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. Quotient disclaims any obligation to update these forward-looking statements.*



**CONTACT:** Chris Lindop, Chief Financial Officer – chris.lindop@quotientbd.com; +41 22 545 52 26

**Quotient Limited**
**Condensed Consolidated Statements Of Comprehensive Loss**
**(in thousands, except share and per share amounts)**
**(unaudited)**

| | Quarter Ended June 30, | |
|---|---|---|
| | **2017** | **2016** |
| **Revenue:** | | |
| Product sales | $ 6,226 | $ 5,717 |
| Other revenues | 600 | — |
| **Total revenue** | 6,826 | 5,717 |
| Cost of revenue | 2,832 | 3,091 |
| **Gross profit** | 3,994 | 2,626 |
| **Operating expenses:** | | |
| Sales and marketing | 1,682 | 1,257 |
| Research and development, net | 12,673 | 11,801 |
| General and administrative expense | 6,545 | 5,946 |
| **Total operating expense** | 20,900 | 19,004 |
| **Operating loss** | (16,906) | (16,378) |
| **Other income (expense)** | | |
| Interest expense, net | (4,210) | (1,171) |
| Other, net | 880 | 1,314 |
| **Other income (expense), net** | (3,330) | 143 |
| **Loss before income taxes** | (20,236) | (16,235) |
| Provision for income taxes | — | — |
| **Net loss** | $ (20,236) | $ (16,235) |
| **Other comprehensive income (loss):** | | |
| Change in fair value of effective portion of foreign currency cash flow hedges | $ 345 | $ (263) |
| Unrealized gain on short-term investments | 38 | — |
| Foreign currency gain (loss) | 1,815 | (3,308) |
| Provision for pension benefit obligation | 43 | 41 |
| **Other comprehensive income (loss)** | 2,241 | (3,530) |
| **Comprehensive loss** | $ (17,995) | $ (19,765) |
| Net loss available to ordinary shareholders - basic and diluted | $ (20,236) | $ (16,235) |
| Loss per share - basic and diluted | $ (0.55) | $ (0.64) |
| Weighted-average shares outstanding - basic and diluted | 36,767,544 | 25,410,598 |

**Quotient Limited**
**Condensed Consolidated Balance Sheets**
**(In Thousands)**
**(Unaudited)**

| | June 30, 2017 | March 31, 2017 |
|---|---|---|
| **ASSETS** | | |
| **Current assets:** | | |
| Cash and cash equivalents | $ 13,008 | $ 4,754 |
| Short-term investments | 27,661 | 16,057 |
| Trade accounts receivable, net | 2,800 | 2,556 |
| Inventories | 14,810 | 13,636 |
| Prepaid expenses and other current assets | 4,682 | 3,629 |
| **Total current assets** | 62,961 | 40,632 |
| Cash reserve account | 5,040 | 5,040 |
| Property and equipment, net | 70,062 | 63,530 |
| Intangible assets, net | 784 | 769 |
| **Total assets** | $ 138,847 | $ 109,971 |
| **LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)** | | |
| **Current liabilities:** | | |
| Accounts payable | $ 10,098 | $ 10,782 |
| Accrued compensation and benefits | 2,846 | 3,641 |
| Accrued expenses and other current liabilities | 13,398 | 13,509 |
| Current portion of lease incentive | 441 | 422 |
| Capital lease obligation | 1,445 | 1,374 |
| **Total current liabilities** | 28,228 | 29,728 |
| Long-term debt | 82,150 | 80,704 |
| Lease incentive, less current portion | 772 | 844 |
| Capital lease obligation, less current portion | 153 | 174 |
| Defined benefit pension plan obligation | 5,535 | 5,337 |
| 7% Cumulative redeemable preference shares | 17,538 | 17,275 |
| **Total liabilities** | 134,376 | 134,062 |
| Total shareholders' equity (deficit) | 4,471 | (24,091) |
| **Total liabilities and shareholders' equity (deficit)** | $ 138,847 | $ 109,971 |

**Quotient Limited**
**Condensed Consolidated Statements of Cash Flows**
**(In Thousands)**
**(Unaudited)**

| | Quarter ended June 30, | |
|---|---|---|
| | **2017** | **2016** |
| ***OPERATING ACTIVITIES:*** | | |
| **Net loss** | $ (20,236) | $ (16,235) |
| **Adjustments to reconcile net loss to net cash provided by operating activities:** | | |
| Depreciation and amortization | 2,464 | 2,286 |
| Share-based compensation | 1,285 | 898 |
| Amortization of lease incentive | (109) | (109) |
| Swiss pension obligation | 172 | 185 |
| Amortization of deferred debt issue costs | 1,446 | 228 |
| Accrued preference share dividends | 263 | 263 |
| **Net change in assets and liabilities:** | | |
| Trade accounts receivable, net | (170) | (204) |
| Inventories | (608) | (560) |
| Accounts payable and accrued liabilities | (2,005) | 1,406 |
| Accrued compensation and benefits | (837) | (152) |
| Other assets | (811) | (1,247) |
| **Net cash used in operating activities** | (19,146) | (13,241) |
| ***INVESTING ACTIVITIES:*** | | |
| Increase in short-term investments | (43,000) | — |
| Realization of short-term investments | 31,434 | — |
| Purchase of property and equipment | (5,436) | (6,579) |
| Purchase of intangible assets | (6) | — |
| **Net cash used in investing activities** | (17,008) | (6,579) |
| ***FINANCING ACTIVITIES:*** | | |
| Repayment of finance leases | (29) | (37) |
| Proceeds from issuance of ordinary shares | 45,273 | — |
| Net cash generated from financing activities | 45,244 | (37) |
| Effect of exchange rate fluctuations on cash and cash equivalents | (836) | (1,860) |
| Change in cash and cash equivalents | 8,254 | (21,717) |
| Beginning cash and cash equivalents | 4,754 | 44,100 |
| Ending cash and cash equivalents | $ 13,008 | $ 22,383 |
| **Supplemental cash flow disclosures:** | | |
| Income taxes paid | $ — | $ — |
| Interest paid | $ 5,068 | $ 679 |