

QUOTIENT LTD

FORM 8-K (Current report filing)

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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): May 22, 2017 (May 22, 2017)

QUOTIENT LIMITED

(Exact name of registrant as specified in its charter)

Jersey, Channel Islands
(State or other jurisdiction
of incorporation)

001-36415
(Commission File Number)

Not Applicable
(IRS Employer
Identification No.)

**Pentlands Science Park
Bush Loan, Penicuik, Midlothian
EH26 OPZ, United Kingdom**
(Address of principal executive offices)

Not Applicable
(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 Operations and Financial Condition.

On May 22, 2017, Quotient Limited issued an earnings release announcing its financial results for the quarter and financial year ended March 31, 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 May 22, 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: May 22, 2017

INDEX TO EXHIBITS

**Exhibit
number**

Description of exhibit

99.1

Earnings Release, dated May 22, 2017.



Quotient Limited Reports Continued Progress on the Commercial Scale-up of MosaiQ and Fourth Quarter and Fiscal Year 2017 Financial Results

- *Initial MosaiQ manufacturing system commissioned and validated*
- *First “commercially ready” MosaiQ Instrument delivered to Quotient*
- *Internal validation of MosaiQ underway , with EU field trials expected in 3QCY17*
- *Fourth quarter revenues of \$5.5 million and Product sales of \$4.7 million, exceeding guidance*
- *\$48 million equity raise successfully completed in April 2017*

JERSEY, Channel Islands, May 22, 2017 (GLOBENEWSWIRE) -- Quotient Limited (NASDAQ:QTNT), a commercial-stage diagnostics company, today reported continued progress on the commercial scale-up of MosaiQ and financial results for its fourth quarter and fiscal year ended March 31, 2017.

“Tremendous progress continues to be made towards the full commercial launch of MosaiQ in Europe later this year. The initial manufacturing system for MosaiQ Microarrays is now commissioned and validated. Working with our partner STRATEC, we have now taken delivery of the first “commercially ready” MosaiQ Instrument” said Paul Cowan, Chairman and Chief Executive Officer of Quotient. “Internal validation studies are now underway for the initial MosaiQ applications, with European field trials scheduled to commence early in the third calendar quarter of 2017. We look forward to sharing the results of the internal validation studies and European field trials when they are completed later this summer.”

MosaiQ Platform

MosaiQ, Quotient's next-generation automation platform for blood grouping and disease screening, represents a transformative and highly disruptive testing platform for transfusion diagnostics, with an established capability to detect antibodies and antigens. Feasibility has also been demonstrated with respect to the detection of nucleic acids (DNA or RNA). Through MosaiQ, Quotient aims to deliver substantial value to donor testing laboratories worldwide with a unified instrument platform to be utilized for blood grouping and both serological and molecular disease screening of donated red blood cells and plasma.

Assay Performance

Assay performance for the initial blood grouping and disease screening applications continues to meet expectations. The Company has taken the opportunity over the past four weeks to further optimize the spot recognition algorithm for the antibody detection assay.

Quotient has commenced formal internal validation studies for the MosaiQ IH Microarray and the MosaiQ SDS Microarray (for CMV and Syphilis). The se studies are designed to mimic the subsequent field trials. This work is expected to be completed in July.

Regulatory and Commercial Milestones

- **European Field Trials** – Quotient expects to commence European field trials in the third calendar quarter of 2017
- **European Regulatory Approval** – Quotient expects to file for European regulatory approval for MosaiQ in the second half of 2017
- **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 mid 2018
- **U.S. Field Trials** – Quotient expects to commence U.S. field trials during the second half of calendar 2017
- **U.S. Regulatory Approval** – Quotient expects to file for U.S. regulatory approval and clearance for MosaiQ around the end of calendar 2017
- **U.S. Commercialization** – If approved for sale, Quotient expects to begin marketing MosaiQ in the U.S. in early 2019

Fiscal Fourth Quarter and Full Year Financial Results

“The conventional reagent business generated record results in terms of revenue and profitability during fiscal 2017, with total revenues growing 20% year-over-year,” said Paul Cowan. “Quotient generated product sales and gross profit growth of 12% and 11%, respectively, during fiscal 2017. We are targeting a continuation of solid growth and profitability for this business in the coming fiscal year.”

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

	Quarter Ended March 31,		Year Ended March 31,	
	2017	2016	2017	2016
Revenue:				
Product sales — OEM Customers	\$ 3,356	\$ 3,072	\$ 14,216	\$ 12,165
Product sales — direct customers and distributors	1,370	1,473	5,911	5,857
Other revenues	800	500	2,100	500
Total revenue	\$ 5,526	\$ 5,045	\$ 22,227	\$ 18,522
Product sales from standing orders (%)	81%	77%	76%	75%
Gross profit	\$ 3,136	\$ 2,487	\$ 11,383	\$ 8,864
Gross profit as a % of total revenue	56.8%	49.3%	51.2%	47.9%
Gross margin on product sales (%)	49.4%	43.7%	46.1%	46.4%
Operating (loss)	\$ (17,739)	\$ (12,845)	\$ (74,059)	\$ (49,088)

Capital expenditures totaled \$20.2 million in fiscal 2017 ("FY17"), compared with \$29.0 million in fiscal 2016 ("FY16"), reflecting continued investment in the Eysins, Switzerland manufacturing facility and manufacturing equipment for MosaiQ consumables, along with expenditures related to the construction of a new conventional reagent manufacturing facility near Edinburgh, Scotland.

Quotient ended FY17 with \$20.8 million in cash and other short term investments, \$80.7 million of long-term debt and \$5.0 million in an offsetting long term cash reserve account. On April 10, 2017, Quotient completed an equity offering raising \$45.2 million, net of expenses.

Outlook for the Fiscal Year Ending March 31, 2018

- Total revenue in the range of \$33 to \$34 million, including other revenue (product development fees) of approximately \$12 million. Forecast other revenue assumes the receipt of milestone payments contingent upon achievement of regulatory approval for certain products under development, including MosaiQ. The receipt of these milestone payments involves risks and uncertainties.
- Product sales of \$21 to \$22 million, compared with FY17 Product sales of \$20 million.
- Operating loss in the range of \$63 to \$68 million, including non-cash charges for depreciation, amortization and stock compensation totaling approximately \$15 million.
- Capital expenditures in the range of \$25-\$30 million.

Product sales in the first quarter of fiscal 2018 are expected to be within the range of \$5.7 to \$6.0 million, compared with \$5.7 million for the first quarter of FY17.

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.

The accompanying condensed consolidated financial statements have been prepared on a basis which assumes that Quotient will continue as a going concern. However, the Company has incurred net losses from operations in each year since it commenced operations in 2007 and had an accumulated deficit of \$193.3 million as of March 31, 2017. Although Quotient's audit is not yet completed, the Company expects that its auditor's report will reference certain conditions concerning the Company's overall liquidity position that raise substantial doubt about its ability to continue as a going concern.

Conference Call

Quotient will host a conference call on Tuesday, May 23 at 8:00 a.m. Eastern Time to discuss its fourth quarter FY17 and FY17 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 May 30 by dialing 1-844-512-2921 in the U.S. or 1-412-317-6671 outside the U.S. The replay access code is 13660555.

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 first quarter and full year fiscal 2018 operating results and capital expenditures 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.

The Quotient logo and MosaiQ are registered trademarks or trademarks of Quotient Limited and its subsidiaries in various jurisdictions.

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 March 31,		Year Ended March 31,	
	2017	2016	2017	2016
Revenue:				
Product sales	\$ 4,726	\$ 4,545	\$ 20,127	\$ 18,022
Other revenues	800	500	2,100	500
Total revenue	<u>5,526</u>	<u>5,045</u>	<u>22,227</u>	<u>18,522</u>
Cost of revenue	2,390	2,558	10,844	9,658
Gross profit	<u>3,136</u>	<u>2,487</u>	<u>11,383</u>	<u>8,864</u>
Operating expenses:				
Sales and marketing	1,294	723	5,660	3,073
Research and development, net	13,585	6,659	57,064	28,781
General and administrative expense	5,996	7,950	22,718	26,098
Total operating expense	<u>20,875</u>	<u>15,332</u>	<u>85,442</u>	<u>57,952</u>
Operating loss	(17,739)	(12,845)	(74,059)	(49,088)
Other income (expense)				
Interest expense, net	(3,351)	(1,159)	(9,903)	(4,151)
Change in financial liability for share warrants	—	—	—	15,857
Other, net	781	4,491	(1,107)	3,504
Other income (expense), net	<u>(2,570)</u>	<u>3,332</u>	<u>(11,010)</u>	<u>15,210</u>
Loss before income taxes	(20,309)	(9,513)	(85,069)	(33,878)
Provision for income taxes	—	—	—	—
Net loss	<u>\$ (20,309)</u>	<u>\$ (9,513)</u>	<u>\$ (85,069)</u>	<u>\$ (33,878)</u>
Other comprehensive income (loss):				
Change in fair value of effective portion of foreign currency cash flow hedges	\$ 247	\$ (111)	\$ (63)	\$ 9
Unrealized gain on short-term investments	\$ 19	\$ —	\$ 19	\$ —
Foreign currency gain (loss)	111	(2,731)	(6,215)	(3,028)
Provision for pension benefit obligation	(539)	(2,755)	(410)	(4,502)
Other comprehensive loss, net	<u>(162)</u>	<u>(5,597)</u>	<u>(6,669)</u>	<u>(7,521)</u>
Comprehensive loss	<u>\$ (20,471)</u>	<u>\$ (15,110)</u>	<u>\$ (91,738)</u>	<u>\$ (41,399)</u>
Net loss available to ordinary shareholders - basic and diluted	\$ (20,309)	\$ (9,513)	\$ (85,069)	\$ (33,878)
Loss per share - basic and diluted	\$ (0.69)	\$ (0.41)	\$ (3.02)	\$ (1.73)
Weighted-average shares outstanding - basic and diluted	29,540,220	23,406,473	28,145,472	19,558,152

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

	March 31,	March 31, 2016
	2017	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,754	\$ 44,100
Short-term investments	16,057	—
Trade accounts receivable, net	2,556	2,269
Inventories	13,636	12,584
Prepaid expenses and other current assets	3,629	2,780
Total current assets	40,632	61,733
Cash reserve account	5,040	—
Property and equipment, net	63,530	57,115
Intangible assets, net	769	902
Total assets	\$ 109,971	\$ 119,750
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 10,782	\$ 7,286
Accrued compensation and benefits	3,641	3,294
Accrued expenses and other current liabilities	13,509	9,180
Current portion of long-term debt	—	1,000
Current portion of lease incentive	422	439
Capital lease obligation	1,374	152
Total current liabilities	29,728	21,351
Long-term debt	80,704	27,910
Lease incentive, less current portion	844	1,316
Capital lease obligation, less current portion	174	1,723
Defined benefit pension plan obligation	5,337	4,502
7% Cumulative redeemable preference shares	17,275	16,225
Total liabilities	134,062	73,027
Commitments and contingencies	—	—
Total shareholders' equity (deficit)	(24,091)	46,723
Total liabilities and shareholders' equity (deficit)	\$ 109,971	\$ 119,750

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

	Year ended March 31,		
	2017	2016	2015
OPERATING ACTIVITIES:			
Net loss	\$ (85,069)	\$ (33,878)	\$ (59,059)
Adjustments to reconcile net loss to net cash provided by operating activities:			
Depreciation, amortization and loss on disposal of fixed assets	9,461	2,945	1,676
Share-based compensation	4,221	2,004	1,138
Amortization of lease incentive	(428)	(434)	(443)
Swiss pension obligation	616	—	—
Amortization of deferred debt issue costs	6,774	1,472	776
Accrued preference share dividends	1,050	1,050	175
Change in financial liability for share warrants	—	(15,857)	22,966
Net change in assets and liabilities:			
Trade accounts receivable, net	(584)	(519)	362
Inventories	(1,766)	(8,126)	(552)
Accounts payable and accrued liabilities	9,960	955	7,358
Accrued compensation and benefits	778	812	772
Other assets	(1,213)	2,603	(1,760)
Net cash used in operating activities	(56,200)	(46,973)	(26,591)
INVESTING ACTIVITIES:			
Increase in short-term investments	(30,009)	—	—
Realization of short-term investments	13,971	—	—
Purchase of property and equipment	(20,155)	(28,906)	(23,854)
Purchase of intangible assets	(71)	(71)	(188)
Net cash used in investing activities	(36,264)	(28,977)	(24,042)
FINANCING ACTIVITIES:			
Proceeds from (repayment of) finance leases	(141)	(39)	195
Proceeds from drawdown of new debt	84,000	15,500	—
Repayment of debt	(33,450)	(500)	—
Debt issue costs	(5,530)	(703)	—
Increase in cash reserve account	(5,040)	—	—
Proceeds from issuance of preference shares	—	—	15,000
Proceeds from issuance of ordinary shares	16,703	71,390	69,879
Net cash generated from financing activities	56,542	85,648	85,074
Effect of exchange rate fluctuations on cash and cash equivalents	(3,424)	(3,123)	(4,108)
Change in cash and cash equivalents	(39,346)	6,575	30,333
Beginning cash and cash equivalents	44,100	37,525	7,192
Ending cash and cash equivalents	<u>\$ 4,754</u>	<u>\$ 44,100</u>	<u>\$ 37,525</u>
Supplemental cash flow disclosures:			
Income taxes paid	\$ —	\$ —	\$ —
Interest paid	\$ 1,702	\$ 2,164	\$ 1,364