

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

JERSEY, Channel Islands, Oct. 31, 2016 (GLOBE NEWSWIRE) -- Quotient Limited (NASDAQ:QTNT), a commercial-stage diagnostics company, today reported further progress on the commercial scale-up of MosaiQ[™] and financial results for its fiscal second guarter and six months ended September 30, 2016.

"Strong progress continues to be made advancing MosaiQ™ towards commercial launch, both in terms of MosaiQ™ Microarray manufacturing and completion of the final MosaiQ™ instrument," said Paul Cowan, Chairman and Chief Executive Officer of Quotient. "Customer feedback regarding MosaiQ™ continues to be extremely positive, following yet another successful showing at the AABB Annual Meeting in late October. While we have experienced a delay in completing planned internal validation studies for MosaiQ™, the prospects for its successful commercialization remain unchanged."

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, antigens and nucleic acid (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.

Quotient showcased a working MosaiQ[™] instrument at the 2016 Annual Meeting of the American Association of Blood Banks (AABB) held in Orlando, Florida on October 22-25. Over 75 delegates from more than 40 donor collection agencies and hospitals, mainly located in the United States, viewed the instrument and received a progress update on the advancement of the MosiaQ[™] platform.

Considerable progress continues to be made on the commercial scale-up of MosaiQ[™], with MosaiQ[™] IH Microarrays for blood grouping now being manufactured routinely at Quotient's Eysins, Switzerland facility. In parallel, internal validation and verification of the MosaiQ[™] instrument has also progressed meaningfully and is nearing completion. The initial MosaiQ[™] SDS Microarray (serological disease screen for the detection of CMV and Syphilis) is in the process of being finalized and ongoing development efforts are focused on completing the full serological disease screening menu.

Quotient continues to work on completing its initial internal validation studies for the MosaiQTM IH Microarray, which it had planned to present at AABB. Completion of these studies was delayed after Quotient identified inconsistencies in the results of early testing. Quotient is currently conducting a comprehensive root-cause investigation to identify the reasons for the unexpected variability. The internal validation studies will recommence following completion of this investigation and correction of any issues identified.

Completion of European field trials and the commercial launch of MosaiQTM in Europe are currently planned for the first half of 2017. Field trials in the United States will commence after the completion of European field trials. Once licensed for sale, MosaiQTM will be the first fully-automated solution for blood grouping, providing for the comprehensive characterization of both donor and patient blood. Quotient intends to simultaneously launch its MosaiQTM IH Microarray into the donor and patient testing markets with its commercial partner, Ortho-Clinical Diagnostics. Launch of the initial MosaiQTM SDS Microarray into the donor testing market will coincide with the launch of the MosaiQTM IH Microarray. Launch of the full MosaiQTM serological disease screening panel is currently planned to commence three to six months after the initial MosaiQTM launch.

Conventional Reagent Business Update

"During the second quarter, strong revenue growth was generated by all key categories of our conventional reagent business, as product sales grew 13% year-over-year," said Paul Cowan. "Our U.S. direct business had another exceptional quarter, with product sales growing 29% year-over-year, driven by the impact of recent product launches, new customers for our reagent red blood cell products and better pricing."

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

	September 30,					September 30,				
		2016	2015		2016			2015		
Revenue:										
Product sales —OEM Customers	\$	3,447	\$	2,784	\$	7,358	\$	6,214		
Product sales — direct customers and distributors		1,397		1,489		3,203		2,909		
Other revenues		1,300		_		1,300		_		
Total revenue	\$	6,144	\$	4,273	\$	11,861	\$	9,123		
Product sales from standing orders (%)		73%		71%		75%		73%		
Gross profit	\$	3,383	\$	2,149	\$	6,009	\$	4,248		
Gross profit as a % of total revenue		55.1%		50.3%		50.7%		46.6%		
Gross margin on product sales (%)		43.0%		50.3%		44.6%		46.6%		
Operating (loss)	\$(17,511)	\$(12,971)	\$	(33,889)	\$(23,464)		

Fiscal Second Quarter 2017 Financial Results

Total revenue in the second quarter of fiscal 2017 ("2QFY17") was \$6.1 million, compared with \$4.3 million in the second quarter of fiscal 2016 ("2QFY16"). Product sales in 2QFY17 were \$4.8 million, compared with \$4.3 million in 2QFY16, representing growth of 13% year-over-year, or 16% excluding the impact of foreign currency translation. The increase was primarily attributable to growth in product sales revenues from original equipment manufacturer ("OEM") customers and incremental direct sales of conventional reagent products to customers in the United States. Quotient also recognized \$1.3 million of product development fees in 2QFY17, which did not occur in 2QFY16.

Gross profit on total revenue was \$3.4 million in 2QFY17, compared with \$2.1 million in 2QFY16. Gross profit in 2QFY17 included \$1.3 million of product development fees for which there were no associated costs. Gross profit on product sales was \$2.1 million in 2QFY17, compared with \$2.1 million in 2QFY16, as the positive impact of better pricing and greater sales volumes was offset by the negative impact of product sales mix and abnormally high levels of waste at Quotient's legacy manufacturing facility in Edinburgh, Scotland. This aging plant will be replaced by a new facility, currently under construction, located outside Edinburgh. Gross margin on product sales was 43.0% in 2QFY17, compared with 50.3% in 2QFY16.

Research and development expense was \$14.5 million in 2QFY17, compared with \$8.4 million in 2QFY16. This increase reflected incremental costs associated with the commercial scale up of MosaiQ[™], including initial production costs that are currently expensed as research and development. General and administrative expense was \$5.1 million in 2QFY17, compared with \$6.0 million in 2QFY16. The decrease was mainly attributable to the allocation of production overhead costs to research and development following the establishment of specific production department cost centers in April 2016. Sales and marketing expense was \$1.3 million in 2QFY17, compared with \$0.8 million in 2QFY16. This increase was mainly attributable to the MosaiQ[™] commercial team, which was established in April 2016.

Net other income was \$0.2 million in 2QFY17, compared with \$8.5 million in 2QFY16. Net other income in 2QFY17 included interest expense of \$1.2 million and foreign exchange gains of \$1.4 million. Net other income in 2QFY16 included interest expense of \$1.1 million, debt refinancing expense of \$0.6 million and a \$10.3 million unrealized gain related to the change in fair value of the warrants issued as part of Quotient's initial public offering.

Net loss attributable to ordinary shareholders for 2QFY17 was \$17.4 million, or a loss of \$0.62 per ordinary share (basic and diluted), compared with a net loss of \$4.4 million, or a loss of \$0.25 per ordinary share (basic and diluted) in 2QFY16.

Capital expenditures totaled \$2.8 million in 2QFY17, compared with \$7.2 million in 2QFY16, reflecting expenditures related to the construction of a new conventional reagent manufacturing facility near Edinburgh, Scotland.

Quotient ended 2QFY17 with \$19.0 million in cash and cash equivalents and \$29.4 million of term debt. On October 14, 2016, Quotient completed a private placement of up to \$120 million of 12% Senior Secured Notes due 2023. Quotient issued \$84.0 million of notes at the initial closing, receiving net proceeds of approximately \$79.0 million after expenses, and repaid all outstanding obligations under its existing loan agreement with MidCap Financial Trust, which amounted to \$33.5 million including fees and expenses. So long as there is no event of default, Quotient will issue an additional \$36.0 million aggregate principal amount of notes to note purchasers upon public announcement of successful field trial results for the MosaiQTM IH Microarray that demonstrates greater than 99% concordance for the detection of blood group antigens and greater than 95% concordance for the detection of blood group antigens and antibodies.

Outlook for the Fiscal Year Ending March 31, 2017

- Total revenue in the range of \$21.7 to \$22.7 million, including other revenue (product development fees) of approximately \$2.1 million (previously \$2.7 million). Forecast other revenue assumes the receipt of milestone payments contingent upon achievement of regulatory approval for certain conventional reagent products under development. The receipt of these milestone payments involves risks and uncertainties.
- Product sales of \$19.6 to \$20.6 million (previously \$19.0 to \$20.0 million), compared with Product sales of \$18.0 million for the fiscal year ended March 31, 2016.
- Operating loss in the range of \$60.0 to \$65.0 million (previously \$55.0 to \$60.0 million).

Product sales in the third quarter of fiscal 2017 are expected to be within the range of \$4.3 to \$4.8 million, compared with \$4.4 million for the third quarter of fiscal 2016.

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, November 1st at 8:30 a.m. Eastern Time to discuss its second quarter fiscal 2017 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 also be webcast live on the Company's website at www.quotientbd.com.

A replay of this conference call will be available through November 8th by dialing 1-844-512-2921 in the U.S. or 1-412-317-6671 outside the U.S. The replay access code is 13648098.

About MosaiQ™

MosaiQ[™] has been designed to offer a breadth of diagnostic tests unmatched by existing commercially available transfusion diagnostic instrument platforms, spanning blood grouping, serological disease screening for donor testing and nucleic acid testing (or molecular disease screening) for donor testing.

Once approved, MosaiQTM will be the first fully automated solution for blood grouping, providing for the comprehensive characterization of both donor and patient blood, with turnaround times significantly quicker than existing methods. Widespread adoption of MosaiQTM is expected to improve patient outcomes through better and easier matching of donor and patient blood, given cost-effective extended antigen typing offered by MosaiQTM. Improved patient outcomes from the use of MosaiQTM include the potential for reduced incidence of adverse events associated with transfusion, particularly alloimmunization, where patients develop antibodies to foreign antigens introduced through transfused blood.

 $MosaiQ^{TM}$ will also offer the opportunity for substantial cost savings and a range of operational efficiencies for donor and patient testing laboratories, including:

- elimination of the need for routine manual testing typically undertaken by highly skilled technicians;
- simplification of required consumables and testing processes;
- consolidation of multiple instrument platforms in donor testing laboratories;
- significant reduction in sample volume requirements;
- reduction in the number of patient/donor samples required, consumables and reagent waste; and
- more streamlined processes for matching donor units to patients.

Quotient expects to develop additional applications for MosaiQTM, starting with nucleic acid testing for donor molecular disease screening, upon completion of assay development for the blood grouping and serological disease screening applications.

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 MosaiQTM 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 MosaiQTM and other new products, current estimates of third quarter and full year fiscal 2017 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.

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

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

	Quarter Ended September 30,				Six Month Septem			
	 2016		2015		2016	2015		
Revenue:								
Product sales	\$ 4,844	\$	4,273	\$	10,561	\$ 9,123		
Other revenues	 1,300		<u> </u>		1,300	 		
Total revenue	6,144		4,273		11,861	9,123		
Cost of revenue	2,761		2,124		5,852	 4,875		
Gross profit	3,383		2,149		6,009	4,248		
Operating expenses:								
Sales and marketing	1,273		774		2,530	1,432		
Research and development, net	14,495		8,381		26,296	15,191		
General and administrative expense	 5,126		5,965		11,072	11,089		
Total operating expense	20,894		15,120		39,898	27,712		
Operating loss	(17,511)		(12,971)		(33,889)	(23,464)		
Other income (expense)								
Interest expense, net	(1,213)		(1,061)		(2,384)	(1,858)		
Change in financial liability for share warrants	_		10,256			12,027		
Other, net	 1,366		(657)		2,680	(1,292)		
Other income, net	 153		8,538		296	8,877		
Loss before income taxes	(17,358)		(4,433)		(33,593)	(14,587)		
Provision for income taxes	 		<u> </u>		<u> </u>			
Net loss	\$ (17,358)	\$	(4,433)	\$	(33,593)	\$ (14,587)		
Other comprehensive income (loss):								
Change in fair value of effective portion of								
foreign currency cash flow hedges	\$ 29	\$	(17)	\$	(234)	\$ 209		
Foreign currency gain (loss)	(594)		(1,561)		(3,903)	1,194		
Provision for pension benefit obligation	 46		<u> </u>		87	 (1,747)		
Other comprehensive loss, net	(519)	_	(1,578)		(4,050)	(344)		

Comprehensive loss	\$	(17,877)	\$ (6,011)	\$	(37,643)	\$	(14,931)
Net loss available to ordinary shareholders					,		
- basic and diluted	\$	(17,358)	\$ (4,433)	\$	(33,593)	\$	(14,587)
Loss per share - basic and diluted	\$	(0.62)	\$ (0.25)	\$	(1.25)	\$	(0.85)
Weighted-average shares outstanding - basic and							
diluted	2	8,123,334	17,416,674	2	26,774,378	•	17,222,221

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

	September 30, 2016		M	arch 31, 2016
ASSETS				
Current assets:				
Cash and cash equivalents	\$	18,999	\$	44,100
Trade accounts receivable, net		3,950		2,269
Inventories		13,403		12,584
Prepaid expenses and other current assets		4,191	_	2,780
Total current assets		40,543		61,733
Property and equipment, net		60,486		57,115
Intangible assets, net		838		902
Total assets	\$	101,867	\$	119,750
LIABILITIES AND SHAREHOLDERS' EQUITY				
Current liabilities:				
Accounts payable	\$	8,183	\$	7,286
Accrued compensation and benefits		3,042		3,294
Accrued expenses and other current liabilities		9,133		9,180
Current portion of long-term debt		7,000		1,000
Current portion of lease incentive		436		439
Capital lease obligation		122		152
Total current liabilities	-	27,916	_	21,351
Long-term debt		22,416		27,910
Lease incentive, less current portion		1,090		1,316
Capital lease obligation, less current portion		1,530		1,723
Defined benefit pension plan obligation		4,733		4,502
7% Cumulative redeemable preference shares		16,750	_	16,225
Total liabilities		74,435		73,027
Commitments and contingencies		_		_
Total shareholders' equity		27,432		46,723
Total liabilities and shareholders' equity	\$	101,867	\$	119,750

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

Six mont	ths ended				
September 30,					
2016	2015				

OPERATING ACTIVITIES:

OFERATING ACTIVITIES.					
Net loss	\$ (33,593)	\$	(14,58	37)
Adjustments to reconcile net loss to net cash provided by operating activities:					
Depreciation and amortization		4,641		90)7
Share-based compensation		1,981		81	14
Amortization of lease incentive		(217)		(22	22)
Swiss pension obligation		344		-	_
Amortization of deferred debt issue costs		506		1,05	56
Accrued preference share dividends		525		52	25
Change in financial liability for share warrants		_		(12,02	27)
Net change in assets and liabilities:					
Trade accounts receivable, net		(1,870)		(28	37)
Inventories		(1,333)		(1,12	25)
Accounts payable and accrued liabilities		1,614		23	33
Accrued compensation and benefits		10		(95	58)
Other assets		(1,629)	_	(83	<u>32</u>)
Net cash used in operating activities	(29,021)		(26,50))3)
INVESTING ACTIVITIES:					
Purchase of property and equipment		(9,427)		(14,06	33)
Purchase of intangible assets		(65)	_		_
Net cash used in investing activities		(9,492)		(14,06	33)
FINANCING ACTIVITIES:					
Proceeds from (repayment of) finance leases		(81)		12	26
Proceeds from drawdown of new debt, net of costs		_		14,29	} 7
Proceeds from issuance of ordinary shares		16,371	_	13,35	52
Net cash generated from financing activities		16,290		27,77	⁷ 5
Effect of exchange rate fluctuations on cash and cash equivalents		(2,878)		92	22
Change in cash and cash equivalents	(25,101)		(11,86	39)
Beginning cash and cash equivalents		44,100		37,52	25
Ending cash and cash equivalents	\$	18,999	\$	25,65	56
Supplemental cash flow disclosures:			_		=
Income taxes paid	\$	_	\$;	_
Interest paid	\$	2,391	\$	78	39

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