August 3, 2015

Quotient Limited Reports First Quarter Fiscal 2016 Financial Results

JERSEY, Channel Islands, Aug. 3, 2015 (GLOBE NEWSWIRE) -- Quotient Limited (NASDAQ:QTNT), a commercial-stage diagnostics company, today reported financial results for its fiscal first quarter ended June 30, 2015.

"Commercial scale-up of MosaiQ™ continued at a rapid pace during the first quarter," said Paul Cowan, Chairman and Chief Executive Officer of Quotient. "Conversion of the Eysins, Switzerland facility for the manufacture of MosaiQ™ consumables is now largely complete and installation of the key manufacturing and bioprocessing systems has commenced. Assays to be incorporated on the MosaiQ™ consumables for both blood grouping and disease screening continue to generate positive performance data, as we begin their transfer to final manufacture. Overall, we remain on track for the commercial launch of MosaiQ™ in Europe during the second half of calendar 2016."

MosaiQ™ Status Update

MosaiQ™, our next-generation automation platform for blood grouping and serological disease screening, is at an advanced stage of development and commercial scale-up. Our current efforts are focused on the installation and validation of the initial MosaiQ™ manufacturing system at our Eysins manufacturing facility and completion of the MosaiQ™ instrument with Stratec Biomedical AG ("STRATEC"), our instrument development partner. We remain on plan to manufacture both the blood grouping and the initial disease screening consumables for European field trials in the first quarter of calendar 2016. Field trials in the United States are planned to commence immediately following completion of the European trials.

We have started the transfer of individual blood grouping assays to production, which we expect to complete by the end of calendar 2015. We expect to transfer the CMV and Syphilis assays to production for inclusion on the initial disease screening consumable in the fourth quarter of calendar 2015. The remaining disease screening assays (HBV, HCV, HIV, HTLV and Chagas) for inclusion on the full disease screening consumable are scheduled to be transferred to production in the first half of calendar 2016.

Design of the MosaiQ™ instrument is now largely complete, with the current focus on software development, including software integration, and manufacturing scale-up. We have received advanced prototype instruments from STRATEC for evaluation purposes, which have met our expected functional requirements. Utilizing these prototype instruments, we plan to complete an internal performance evaluation study for MosaiQ™ (involving ~600 known samples) in the third quarter of calendar 2015. We expect to receive field trial versions of the MosaiQ™ instrument before the end of calendar 2015, which will be subject to further software upgrades prior to the commencement of field trials.

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

Conventional Reagent Business Update

"Our conventional reagent business progressed largely to plan during the first quarter of fiscal 2016 and began to play a key role in the commercial scale-up of MosaiQ™ through the production of reagent antibodies for incorporation as assays on the MosaiQ™ blood grouping consumable," said Paul Cowan. "While the business continues to feel the impact of adverse exchange rate movements on both revenues and gross profit, we expect both growth and profitability to improve throughout the remainder of fiscal 2016."

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

	Quarter ended June 30	
	2015	2014
Revenue:		

Product sales —OEM Customers	$ 3,430	$ 3,806
Product sales — direct customers and distributors	1,420	1,461
Other revenues	—	650
Total revenue	**$ 4,850**	**$ 5,917**
Product sales from standing orders (%)	74%	71%
Gross profit	**$ 2,099**	**$ 3,466**
Gross profit as a % of total revenue	43.3%	58.6%
Gross margin on product sales (%)	43.3%	53.5%
Operating (loss)	**$ (10,493)**	**$ (4,406)**

Fiscal First Quarter 2016 Financial Results

Total revenue in the first quarter of fiscal 2016 ("**1QFY16**") was $4.9 million, compared with $5.9 million in the first quarter of fiscal 2015 ("**1QFY15**"). Product sales in 1QFY16 were $4.9 million, compared with $5.3 million in 1QFY15. The decrease was attributable to a $0.5 million negative impact of a stronger U.S. dollar relative to the British Pound and Euro and lower shipments of bulk antisera to OEM customers. During 1QFY16, biomanufacturing capacity traditionally available for OEM production was allocated to the production of reagent antibodies for incorporation as assays on the MosaiQ™ blood grouping consumable. Quotient also recognized $650,000 of product development fees in 1QFY15, which did not recur in 1QFY16.

Gross profit on Total revenue was $2.1 million in 1QFY16, compared with $3.5 million in 1QFY15. Gross profit in 1QFY15 included $650,000 of product development fees for which there were no associated costs. Gross profit on Product sales was $2.1 million in 1QFY16, compared with $2.8 million in 1QFY15. Gross margin on Product sales was 43.3% in 1QFY16, compared with 53.5% in 1QFY15, reflecting the impact of adverse exchange rate movements, higher shipping costs, and incremental conventional reagent manufacturing costs.

Research and development expense was $6.8 million in 1QFY16, compared with $3.7 million in 1QFY15. This increase reflects incremental costs associated with the commercial scale-up of MosaiQ™, including initial production costs (primarily staff and ra materials), which are currently expensed as research and development. Sales and marketing expense was $0.7 million in 1QFY16, compared with $0.7 million in 1QFY15. General and administrative expense was $5.1 million in 1QFY16, compared with $3.5 million in 1QFY15. This increase reflected greater personnel-related costs, increased facility rental charges and increased corporate costs.

Net other income was $0.3 million in 1QFY16, compared with $1.8 million in 1QFY15. Net other income in 1QFY16 included interest expense of $0.8 million, foreign exchange losses of $0.6 million and a $1.8 million unrealized gain related to the change in fair value of the warrants issued as part of our initial public offering ("IPO"). Net other income in 1QFY15 included interest expense of $0.5 million, foreign exchange losses of $0.2 million and a $3.6 million unrealized gain related to the change in fair value of the warrants issued as part of our IPO. Net other income in 1QFY15 also included an exceptional charge of $0.6 million related to the portion of fees associated with our IPO that were attributable to the issuance of ordinary share warrants and an expense of $0.4 million related to the settlement of a legal dispute.

Net loss attributable to ordinary shareholders for 1QFY16 was $10.2 million, or a loss of $0.60 per ordinary share (basic and diluted), compared with a net loss of $2.6 million, or a loss of $0.20 per ordinary share (basic and diluted) in 1QFY15.

We ended 1QFY16 with $21.3 million in cash and equivalents. Capital expenditures totaled $6.9 million in 1QFY16, compared with $4.9 million in 1QFY15, reflecting investment in the Eysins manufacturing facility and manufacturing equipment for MosaiQ™ consumables.

Outlook for the Fiscal Year Ending March 31, 2016

- Total revenue in the range of $19.0 to $20.0 million, including Other revenue (product development fees) of $1.9 million.
- Product sales of $17.0 to $18.0 million, compared with FY15 revenues of $17.7 million. For fiscal 2016, Product sales are forecast to be negatively impacted by adverse exchange rate movements, reducing reported Product sales by approximately 5%, or $1.0 million, using July 29, 2015 exchange rates.
- Operating loss in the range of $50.0 to $55.0 million.

Product sales in the second quarter of fiscal 2016 are expected to be within the range of $3.7 to $4.2 million, compared with

$4.5 million for the second quarter of fiscal 2015. Product sales are forecast to be negatively impacted by adverse exchange rate movements, reducing reported Product sales by approximately 10%, or $0.4 million, using July 29, 2015 exchange rates.

The above outlook excludes the impact of unrealized gains or losses associated with any change in the fair market value of the warrants issued as part of our IPO.

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, we expect 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 we will continue as a going concern. However, we have incurred net losses and negative cash flows from operations in each year since we commenced operations in 2007, and we expect our operating losses to continue for at least the next two years as we continue our investment in the development and commercialization of MosaiQ™. We ended 1QFY16 with $21.3 million in cash and cash equivalents. Our operating plans for the fiscal year ending March 31, 2016 reflect an expectation that substantially all of our outstanding warrants from our initial public offering, which expire on October 25, 2015, will be exercised before that date. If significant exercises of these warrants do not occur, we may need or decide to raise additional funds through public or private debt or equity financing or through other means. If we are unable to obtain needed financing on acceptable terms or otherwise, we may not be able to implement our business plan.

As noted in our separate press release dated August 3, 2015, we entered into an amended agreement with MidCap Financial LLC ("MidCap") on August 3, 2015 to expand our existing secured term loan facility from $15.0 million to $30.0 million. MidCap also agreed to make available additional credit facilities totaling $20.0 million, subject to certain conditions. We and MidCap originally entered into a $15 million secured term loan facility on December 6, 2013, which had subsequently been paid down to approximately $14.5 million as of August 3, 2015. We received net proceeds in the aggregate amount of $14.8 million, which will be used for working capital purposes.

Conference Call

We will host a conference call on Tuesday, August 4 at 8:30 a.m. Eastern Time to discuss our fiscal 2016 first quarter financial results. Participants may access the call by dialing 1-855-327-6837 in the U.S. or 1-778-327-3988 outside the U.S. The call will be webcast live on our website at www.quotientbd.com.

A replay of this conference call will be available through August 11 by dialing 1-877-870-5176 in the U.S. or 1-858-384-5517 outside the U.S. The replay access code is 908040.

About MosaiQ™

We have designed MosaiQ™ to offer a breadth of diagnostic tests that is unmatched by existing commercially available transfusion diagnostic instrument platforms. Time to result for MosaiQ™ will be significantly quicker than existing methods for extended antigen typing and antibody identification and is expected to be equivalent to the time to result for current instrument platforms performing basic antigen typing. We also 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, wh the patient develops antibodies to foreign antigens introduced to the body through transfused blood. MosaiQ™ will also offer the opportunity for substantial cost savings and a range of operational efficiencies for donor and patient testing laboratories, including:

- comprehensive characterization of blood-group antigens and antibodies present in donor or patient blood, eliminating 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 of sample volume requirements;
- reduction of consumable and reagent waste; and
- more streamlined processes for matching donor units to patients.

About Quotient Limited

Quotient is an established, 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; Newtown, Pennsylvania; and Eysins, Switzerland.

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 include statements regarding our expectations of continued growth, the development, regulatory approval, commercialization and impact of MosaiQ™ and other new products, current estimates of fiscal 2016 operating results and expectations regarding our future funding sources, including proceeds from exercises of our outstanding warrants. 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.

Quotient Limited

Condensed Consolidated Statements Of Comprehensive Loss

(in thousands, except share and per share amounts)

(unaudited)

	Quarter ended June 30	
	2015	**2014**
Revenue:		
Product sales	$ 4,850	$ 5,267
Other revenues	—	650
Total revenue	4,850	5,917
Cost of revenue	2,751	2,451
Gross profit	2,099	3,466
Operating expenses:		
Sales and marketing	658	697
Research and development, net	6,810	3,685
General and administrative expense	5,124	3,490
Total operating expense	12,592	7,872
Operating loss	(10,493)	(4,406)
Other income (expense)		
Interest expense, net	(797)	(534)
Change in financial liability for share warrants	1,771	3,579
Other, net	(635)	(1,255)
Other income, net	339	1,790
Loss before income taxes	(10,154)	(2,616)
Provision for income taxes	—	—

Net loss	$ (10,154)	$ (2,616)
Other comprehensive income (loss):		
Change in fair value of effective portion of foreign currency cash flow hedges	$ 226	$ (94)
Foreign currency gain	2,755	373
Other comprehensive income, net	2,981	279
Comprehensive loss	$ (7,173)	$ (2,337)
Net loss available to ordinary shareholders - basic and diluted	$ (10,154)	$ (2,616)
Loss per share - basic and diluted	$ (0.60)	$ (0.20)
Weighted-average shares outstanding - basic and diluted	17,025,631	12,838,085

Quotient Limited

Condensed Consolidated Balance Sheets

(In Thousands)

(Unaudited)

	June 30, 2015	**March 31, 2015**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 21,259	$ 37,525
Trade accounts receivable, net	2,214	1,808
Inventories	5,012	4,608
Prepaid expenses and other current assets	5,738	6,129
Total current assets	34,223	50,070
Property and equipment, net	38,083	29,733
Intangible assets, net	988	950
Other non-current assets	266	366
Total assets	$ 73,560	$ 81,119
LIABILITIES AND SHAREHOLDERS' DEFICIT		
Current liabilities:		
Accounts payable	$ 8,844	$ 7,238
Accrued compensation and benefits	2,723	2,565
Accrued expenses and other current liabilities	7,532	8,787
Financial liability in respect of share warrants	29,209	31,011
Current portion of long-term debt	6,000	4,500
Current portion of lease incentive	452	435
Capital lease obligation	254	239
Total current liabilities	55,014	54,775
Long-term debt	9,305	10,768
Lease incentive, less current portion	1,695	1,740
Capital lease obligation, less current portion	469	276
7% Cumulative redeemable preference shares	15,438	15,175
Total liabilities	81,921	82,734
Commitments and contingencies	—	—
Total shareholders' deficit	(8,361)	(1,615)
Total liabilities and shareholders' deficit	$ 73,560	$ 81,119

Quotient Limited

Condensed Consolidated Statements of Cash Flows

(In Thousands)

(Unaudited)

	Quarter ended June 30,	
	2015	**2014**
OPERATING ACTIVITIES:		
Net loss	$ (10,154)	$ (2,616)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation and amortization	398	282
Share-based compensation	337	226
Amortization of lease incentive	(111)	(119)
Amortization of deferred debt issue costs	194	198
Accrued preference share dividends	263	—
Change in financial liability for share warrants	(1,771)	(3,579)
Net change in assets and liabilities:		
Trade accounts receivable, net	(300)	(757)
Inventories	(134)	28
Accounts payable and accrued liabilities	(400)	(45)
Accrued compensation and benefits	8	(108)
Other assets	722	1,730
Net cash used in operating activities	(10,948)	(4,760)
INVESTING ACTIVITIES:		
Purchase of property and equipment	(6,894)	(4,920)
Net cash used in investing activities	(6,894)	(4,920)
FINANCING ACTIVITIES:		
Proceeds from finance leases	177	91
Proceeds from issuance of ordinary shares	59	34,280
Net cash generated from financing activities	236	34,371
Effect of exchange rate fluctuations on cash and cash equivalents	1,340	94
Change in cash and cash equivalents	(16,266)	24,785
Beginning cash and cash equivalents	37,525	7,192
Ending cash and cash equivalents	$ 21,259	$ 31,977
Supplemental cash flow disclosures:		
Income taxes paid	$ —	$ —
Interest paid	$ 344	$ 337

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Source: Quotient Limited