

Quotient Limited Reports Third Quarter Fiscal 2022 Results and Provides Business Update

- **MosaiQ™ Solution:**
 - **Transfusion Diagnostics:** The Notified Body completed the assessment of the Company's technical dossier and has advised that it will recommend the MosaiQ Expanded Immunochemistry (IH) microarray for CE marking approval;
 - **Commercial Execution:** In anticipation of CE marking, the Company's Commercial team is preparing to submit more than 20 tender responses within the EU over the next 18-24 months; At the same time, the Company is actively pursuing distribution partnerships in the EU, Middle East and Africa;
 - **Manufacturing & Operations:** Scale up in progress to support the anticipated MosaiQ commercial launch; Finalized decision on second manufacturing line to meet targeted market demand;
 - **Scientific & Medical Affairs:** Expansion of Innovator's Circle including new partner, Blood Assurance; Successful Scientific Advisory Board (SAB) virtual event with KOLs from US & Europe;
 - **Clinical Diagnostics:** Internal product development program in place; engaged with potential industry partners to fast-track allergy and autoimmune microarray menu development.
- **Alba by Quotient:** Submitted first Alba by Quotient IVDR filing. The new distributor partners for MosaiQ are expected to sell Alba by Quotient portfolio expanding Alba's geographic footprint.
- **Financial Position:** \$10.2 million revenue recorded in the quarter (representing 16% year-over-year growth); raising FY outlook for Alba sales to \$36 million - \$37 million; cash and short-term investments of \$103.8 million.

JERSEY, Channel Islands, February 8, 2022 (GLOBE NEWSWIRE) -- Quotient Limited (NASDAQ:QTNT), a commercial-stage diagnostics company (Quotient or the Company), headquartered in Eysins, Switzerland, today reported its third quarter fiscal 2022 key financial results and furnished an update on recent business developments.

MosaiQ Solution

Transfusion Diagnostics:

Expanded Immunochemistry (IH) Microarray: The regulatory authority designated under EU regulations to evaluate the IH microarray (Notified Body) has completed the assessment of the Company's technical dossier and has advised that it will recommend the MosaiQ Expanded Immunochemistry (IH) microarray for CE marking approval. The Company continues to expect to receive the CE mark in Q1 CY22.



“As we continue to expect EU regulatory approval in the first quarter of calendar year of 2022, we are very excited to continue to drive our commercial efforts globally. We look forward to partnering with our customers and create economic and clinical value to revolutionize patient care,” said Manuel O. Méndez, Chief Executive Officer of Quotient.

Commercial Execution:

A diversified global presence is key to the Company’s go-to-market strategy. The Company continues to make progress on both its tenders and distribution strategy.

The Company has identified over 20 IH tenders which the Company intends to pursue in the EU that are expected to become available over the next 18-24 months. Quotient remains active in preparing for tenders in the rest of the world where CE marking is accepted.

Additionally, the Company is actively discussing commercial distribution offers with potential partners to form a network across the EU, Middle East, and Africa for the MosaiQ solution.

Manufacturing & Operations:

The Company’s manufacturing facility in Eysins, Switzerland is preparing for the commercial launch of MosaiQ with the view to fulfilling anticipated customer demand. The Company has sufficient instruments for initial expected demand and has placed orders for additional MosaiQ instruments for the second half of 2022.

Quotient has finalized the decision on a second manufacturing line based on market access and targeted market demand.

Scientific & Medical Affairs:

The Company’s Innovator’s Circle initiative aims to strengthen understanding and acceptance of the MosaiQ solution by sharing scientific and medical evidence through strategic partnerships. *Blood Assurance*, a full-service regional blood center serving healthcare facilities in Tennessee, Georgia, Alabama, Kentucky, and North Carolina, recently agreed to participate in the Innovator’s Circle initiative.

As part of the Investigator Initiated Research Program, the Company is in the contracting phase in developing countries to support local research. In conjunction with these activities, the Company held a virtual Scientific Advisory Board (SAB) meeting where eight industry experts met with senior Company leaders to create a platform to highlight innovative advances and become involved in discussions on the future strategic potential of the MosaiQ solution.

Clinical Diagnostics:

The Company intends to leverage the capabilities of the MosaiQ platform to serve targeted clinical diagnostics markets. As previously reported, Quotient is initially focused on allergy and autoimmune which is an estimated \$4 billion addressable market opportunity.



The Company continues to build internal research & product development capabilities and to pursue potential third-party collaborations to accelerate the allergy & autoimmune product development. Additionally, the Company has identified initial microarray menus for both allergy & autoimmune educated by feedback from Key Opinion Leaders (KOLs), potential customers, and market research.

Alba by Quotient:

The Company submitted the first IVDR filing this quarter. The Company expects that when new distributors for MosaiQ are appointed, they will also market Alba by Quotient reagents, thereby expanding Alba's geographical footprint.

Financial Position:

The Company reported cash and short-term investments of \$103.8 million that will allow the Company to continue support of the MosaiQ pipeline and commercialize the MosaiQ platform when the Expanded Immunohematology microarray CE marking is obtained.

During the quarter the Company received \$2.2 million related to the Credit Suisse Supply Chain Finance funds.

Fiscal Third Quarter Financial Results

The Alba by Quotient reagent business generated product sales of \$10.2 million in the third quarter of FY 2022, up 21% from the quarter ended December 31, 2020. OEM sales increased by 30% and sales to direct customers and distributors were up 5% vs. Q3 FY 2021. In the quarter ended December 31, 2021, gross margin on product sales was at 22% compared to the gross margin of 43% reported in the quarter ended December 31, 2020. Excluding the impact of the impairment of certain MosaiQ inventory, the Company recorded a gross margin of 47% vs 43%.

Key revenue and profit results are summarized below (expressed in thousands, except percentages).

	Quarter ended December 31,		Nine months ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product sales —OEM customers	\$ 7,174	\$ 5,536	\$ 18,999	\$ 16,754
Product sales — direct customers and distributors	2,983	2,846	9,407	8,417
Product sales – MosaiQ	15	358	91	1,036
Other revenues	—	11	231	7,534
Total revenue	\$ 10,172	\$ 8,751	\$ 28,728	\$ 33,741
Product sales from standing orders (%)	63%	70%	65%	69%
Gross profit	\$ 2,244	\$ 3,781	\$ 11,149	\$ 18,858
Gross profit as a % of total revenue	22%	43%	39%	56%
Gross margin on product sales (%)	22%	43%	38%	43%
Operating (loss)	\$ (31,251)	\$ (21,590)	\$ (76,962)	\$ (54,239)

Total operating expenses for the quarter increased by \$8.1 million or 32% compared to the third quarter of the prior fiscal year. This increase is driven by \$3.8 million of legal and banking fees associated with the amendment to our Senior Notes Indenture and \$4.2M of stock-based compensation and transition costs associated with the executive management team.

Capital expenditures totaled \$0.6 million in the quarter ended December 31, 2021, compared with \$1.5 million in the quarter ended December 31, 2020.

Interest expense for the quarter increased by \$0.2 million compared to Q3 of FY 2021. The higher interest expense recognized in the current period is driven by the issuance of our Convertible Notes in fiscal year 2022.

As at December 31, 2021 Quotient had \$103.8 million in cash and short-term investments and \$228.7 million of debt and \$8.3 million in restricted cash.

Outlook for the Fiscal Year Ending March 31, 2022

- The Company now expects that total product sales of Alba by Quotient reagents in the current fiscal year will be in the range of \$36 million to \$37 million compared to product sales in FY 2021 of \$34.5 million.
- Capital expenditures for fiscal year 2022 are expected to be in the range of \$5 to \$8 million.
- The Company estimates that cash used for operations for the fourth quarter of fiscal year 2022 is in the range of \$6.5 to \$7.5 million per month (excluding debt service cost and capital expenditures).

The Company is not providing guidance on the size of the operating loss it expects to report for the current fiscal year.

Alba by Quotient 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 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 \$699.1 million as of December 31, 2021. The Company expects to include a disclosure within its Quarterly Report on Form 10-Q in respect of 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 February 8th, 2022, at 8:00 a.m. Eastern Time to provide a business update. 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 access code is 13724411. 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 February 16th, 2022, by dialing 1-844-512-2921 in the U.S. or 1-412-317-6671 outside the U.S. The replay access code is 13724411.

About Quotient Limited

Building on over 30 years of experience in transfusion diagnostics, Quotient is a commercial-stage diagnostics company committed to delivering solutions that it believes reshape the way diagnostics are practiced. MosaiQ, Quotient's proprietary multiplex microarray technology, offers the world's first fully automated, consolidated testing platform, allowing for multiple tests across different modalities. MosaiQ is designed to be a game-changing solution, which Quotient believes will increase efficiencies, improve clinical practice, deliver significant workflow improvements, and create operational cost savings to laboratories around the world. Quotient's operations are based in Eysins, Switzerland, Edinburgh, Scotland 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 (including the potential for using the Company's MosaiQ technology to infectious disease diagnostics), current estimates of fourth quarter and full year fiscal 2022 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 proceedings; continued or worsening adverse conditions in the general domestic and global economic markets, including as a result of the global COVID-19 pandemic; 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, Quotient MosaiQ and MosaiQ are registered trademarks or trademarks of Quotient Limited and its subsidiaries in various jurisdictions.

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

	Quarter ended December 31,		Nine months ended December 31,	
	2021	2020	2021	2020
Revenue:				
Product sales	10,172	\$ 8,740	\$ 28,497	\$ 26,207
Other revenues	—	11	231	7,534
Total revenue	10,172	8,751	28,728	33,741
Cost of revenue	(7,928)	(4,970)	(17,579)	(14,883)
Gross profit	2,244	3,781	11,149	18,858
Operating expenses:				
Sales and marketing	(2,878)	(2,283)	(8,011)	(6,757)
Research and development, net of government grants	(13,260)	(14,350)	(42,545)	(38,508)
General and administrative expense:				
Compensation expense in respect of share options and management equity incentives	(2,319)	(1,214)	(5,546)	(3,498)
Other general and administrative expenses	(15,038)	(7,524)	(32,009)	(24,334)
Total general and administrative expense	(17,357)	(8,738)	(37,555)	(27,832)
Total operating expense	(33,495)	(25,371)	(88,111)	(73,097)
Operating loss	(31,251)	(21,590)	(76,962)	(54,239)
Other (expense) income:				
Interest expense, net	(9,559)	(9,404)	(21,914)	(22,632)
Other, net	(3,507)	617	677	6,179
Other expense, net	(13,066)	(8,787)	(21,237)	(16,453)
Loss before income taxes	(44,317)	(30,377)	(98,199)	(70,692)
Provision for income taxes	(504)	(1,303)	(1,019)	(999)
Net loss	\$ (44,821)	\$ (31,680)	\$ (99,218)	\$ (71,691)
Other comprehensive income (loss):				
Change in fair value of foreign currency cash flow hedges	\$ (37)	\$ 295	\$ (380)	\$ 571
Change in unrealized gain on short-term investments	—	111	(193)	(372)
Foreign currency gain (loss)	788	1,606	2,798	(2,026)
Provision for pension benefit obligation	15	13	44	(135)
Other comprehensive loss, net	766	2,025	2,269	(1,962)
Comprehensive loss	\$ (44,055)	\$ (29,655)	\$ (96,949)	\$ (73,653)
Net loss available to ordinary shareholders - basic and diluted	\$ (44,821)	\$ (31,680)	\$ (99,218)	\$ (71,691)
Loss per share - basic and diluted	\$ (0.44)	\$ (0.31)	\$ (0.98)	\$ (0.81)
Weighted-average shares outstanding - basic and diluted	102,127,141	101,016,040	101,695,746	88,512,823

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

	December 31, 2021	March 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 85,060	\$ 45,673
Short-term investments	18,719	65,999
Trade accounts receivable, net	6,146	5,323
Inventories	22,759	22,011
Prepaid expenses and other current assets	6,771	4,870
Total current assets	<u>139,455</u>	<u>143,876</u>
Restricted cash	8,309	9,024
Property and equipment, net	34,950	39,071
Operating lease right-of-use assets	20,405	22,011
Intangible assets, net	553	619
Deferred income taxes	240	255
Other non-current assets	4,864	4,956
Total assets	<u>\$ 208,776</u>	<u>\$ 219,812</u>
LIABILITIES AND SHAREHOLDERS' EQUITY (DEFICIT)		
Current liabilities:		
Accounts payable	\$ 3,253	\$ 4,659
Accrued compensation and benefits	7,155	12,343
Accrued expenses and other current liabilities	10,037	14,009
Current portion of long-term debt	—	24,167
Current portion of operating lease liability	3,113	3,446
Current portion of finance lease obligation	617	835
Total current liabilities	<u>24,175</u>	<u>59,459</u>
Long-term debt, less current portion	228,670	145,059
Derivative liabilities	28,984	—
Operating lease liability, less current portion	20,093	20,907
Finance lease obligation, less current portion	408	445
Deferred income taxes	2,216	1,152
Defined benefit pension plan obligation	7,577	6,896
7% Cumulative redeemable preference shares	22,263	21,475
Total liabilities	<u>334,386</u>	<u>255,393</u>
Commitments and contingencies		
Shareholders' equity (deficit):		
Ordinary shares (nil par value) 102,510,717 and 101,264,412 issued and outstanding at December 31, 2021 and March 31, 2021 respectively	540,732	540,813
Additional paid in capital	45,117	38,116
Accumulated other comprehensive loss	(12,329)	(14,598)
Accumulated deficit	(699,130)	(599,912)
Total shareholders' equity (deficit)	<u>(125,610)</u>	<u>(35,581)</u>
Total liabilities and shareholders' equity (deficit)	<u>\$ 208,776</u>	<u>\$ 219,812</u>

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

	Nine months ended December 31,	
	2021	2020
OPERATING ACTIVITIES:		
Net loss	\$ (99,218)	\$ (71,691)
Adjustments to reconcile net loss to net cash provided by operating activities:		
Depreciation, amortization and loss on disposal of fixed assets	5,696	6,354
Share-based compensation	4,738	3,498
Increase in deferred lease rentals	505	512
Swiss pension obligation	493	776
Amortization of deferred debt issue costs and discount	6,377	9,728
Change in fair value of derivative liabilities	(3,926)	—
Accrued preference share dividends	788	788
Income taxes	1,109	999
Net change in assets and liabilities:		
Trade accounts receivable, net	(879)	1,268
Inventories	(468)	(1,218)
Accounts payable and accrued liabilities	(3,805)	(4,601)
Accrued compensation and benefits	(5,239)	(2,825)
Other assets	(2,344)	(330)
Net cash used in operating activities	(96,173)	(56,742)
INVESTING ACTIVITIES:		
Increase in short-term investments	(4,500)	(72,247)
Realization of short-term investments	51,425	57,683
Purchase of property and equipment	(2,282)	(3,602)
Net cash provided by investing activities	44,643	(18,166)
FINANCING ACTIVITIES:		
Repayment of finance leases	(528)	(491)
Proceeds from issuance of long-term debt	104,222	—
Debt issuance costs	(3,732)	—
Repayment of long-term debt	(12,083)	—
(Cost of) proceeds from issuance of ordinary shares and warrants	(81)	80,888
Net cash provided by financing activities	87,798	80,397
Effect of exchange rate fluctuations on cash and cash equivalents	2,404	(5,982)
Change in cash and cash equivalents	38,672	(493)
Beginning cash and cash equivalents	54,697	12,940
Ending cash and cash equivalents	<u>\$ 93,369</u>	<u>\$ 12,447</u>
Supplemental cash flow disclosures:		
Reconciliation of cash, cash equivalents and restricted cash:		
Cash and cash equivalents	85,060	3,401
Restricted cash	8,309	9,046
Total cash, cash equivalents and restricted cash	<u>\$ 93,369</u>	<u>\$ 12,447</u>