TransMedics Reports Third Quarter 2021 Financial Results

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ANDOVER, Mass., Nov. 9, 2021 /PRNewswire/ -- TransMedics Group, Inc. ("TransMedics") (Nasdaq: TMDX), a medical technology company that is transforming organ transplant therapy for patients with end-stage lung, heart, and liver failure, today reported financial results for the quarter ended September 30, 2021.

Recent Highlights

- Net revenue of $5.4 million in the third quarter of 2021, a 24% decrease compared to the third quarter of 2020, driven primarily by the expiry of revenue contribution from clinical trials
- Received FDA 510(k) clearance for OCS Lung cold flush solution on July 29, 2021
- Received FDA premarket approval (PMA) for OCS Heart System on September 3, 2021
- Received FDA premarket approval (PMA) for OCS Liver System on September 28, 2021
- Announced positive top line results from the U.S. randomized OCS DCD Heart trial

"We achieved two critical milestones in the third quarter with the FDA approval of OCS Heart and OCS Liver. With these approvals, we will leverage our unique competitive and regulatory positions to laser focus the organization on commercial growth in 2022 as we embark on a higher growth trajectory for TransMedics," said Waleed Hassanein, MD, President and Chief Executive Officer. "With unrivaled OCS technology, three FDA approved transplant indications with broad labeling, solid operational footing, and our National OCS Program, we are better positioned than ever to deliver on our growth goals and transform organ transplantation."

Third Quarter 2021 Financial Results
Net revenue for the third quarter of 2021 was $5.4 million, a 24% decrease compared to $7.1 million in the third quarter of 2020. The decrease was due primarily to the discontinuance of OCS Heart and OCS Liver clinical trial revenue prior to receipt of FDA approvals for both systems in September 2021.

Gross margin for the third quarter of 2021 was 70% as compared to 71% in the third quarter of 2020.

Operating expenses for the third quarter of 2021 were $15.5 million compared to $9.6 million in the third quarter of 2020. The increase in operating expense was driven by increased investment in the company's National OCS Program, which is a comprehensive organ retrieval and management service, as well as increases in stock compensation expense, and expenses associated with preparing for two FDA advisory committee panels.

Net loss for the third quarter of 2021 was $13.0 million compared to $5.1 million in the third quarter of 2020.

Cash, cash equivalents and marketable securities were $102.9 million as of September 30, 2021.

2021 Financial Outlook
TransMedics expects net revenue for the full-year 2021 to be in the range of $27.6 million to $28.6 million, which represents 8% to 12% growth compared to the company's prior year net revenue.

Webcast and Conference Call Details
The TransMedics management team will host a conference call beginning at 4:30 p.m. ET / 1:30 p.m. PT on Tuesday, November 9, 2021. Investors interested in listening to the conference call may do so by dialing (833) 378-1026 for domestic callers or (236) 712-2500 for international callers, followed by Conference ID: 3667734. A live and archived webcast of the event will be available on the "Investors" section of the TransMedics website at www.transmedics.com.

About TransMedics Group, Inc.
TransMedics is the world's leader in portable extracorporeal warm perfusion and assessment of donor organs for transplantation. Headquartered in Andover, Massachusetts, the company was founded to address the unmet need for more and better organs for transplantation and has developed technologies to preserve organ quality, assess organ viability prior to transplant, and potentially increase the utilization of donor organs for the treatment of end-stage heart, lung, and liver failure.

Forward-Looking Statements
This press release contains forward-looking statements with respect to, among other things, our operations and financial performance and expected timing of regulatory approvals for our OCS products. These forward-looking statements are subject to a number of risks, uncertainties and assumptions. Moreover, we operate in a very competitive and rapidly changing environment and new risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in or implied by any forward-looking statements we may make. In light of these risks, uncertainties and assumptions, the forward-looking events and circumstances discussed in this press release may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. Some of the key factors that could cause actual results to differ include: that we continue to incur losses; our need to raise additional funding; our existing and any future indebtedness, including our ability to comply with affirmative and negative covenants under our credit agreement to which we will remain subject to until maturity, and our ability to obtain additional financing or refinance existing debt on favorable terms or at all; the fluctuation of our financial results from quarter to quarter; our ability to use net operating losses and research and development credit carryforwards; our dependence on the success of the OCS; the rate and degree of market acceptance of the OCS, including our efforts to develop our National OCS program; our ability to educate patients, surgeons, transplant centers and private payors of benefits offered by the OCS; the impact of the outbreak of the novel strain of coronavirus and associated containment and remediation efforts; our ability to improve the OCS platform and to develop the next generation of our OCS technology platform; our dependence on a limited number of customers for a significant portion of our net revenue; the timing of and our ability to obtain and maintain regulatory approvals or clearances for our OCS products; our ability to adequately respond to FDA follow-up inquiries in a timely manner; the performance of our third-party suppliers and manufacturers; the timing or results of post-approval studies and any clinical trials for the OCS; our manufacturing, sales, marketing and clinical support capabilities and strategy; attacks against our information technology infrastructure; the economic, political and other risks associated with our foreign operations; our ability to attract and retain key personnel; our ability to protect, defend, maintain and enforce our intellectual property rights relating to the OCS and avoid allegations that our products infringe, misappropriate or otherwise violate the intellectual property rights of third parties; our ability to obtain and maintain regulatory approvals or clearance for our OCS products; the pricing of the OCS, as well as the reimbursement coverage for the OCS in the United States and internationally; regulatory developments in the United States, European Union and other jurisdictions; the extent and success of competing products that are or may become available; the impact of any product recalls or improper use of our products; our use of proceeds from our equity offerings; our estimates regarding revenues, expenses and needs for additional financing; and the risks identified under the heading "Risk Factors" and elsewhere in our annual report on Form 10-K for the year ended December 31, 2020, our quarterly reports on Form 10-Q, and in any subsequent filings with the Securities and Exchange Commission ("SEC"). Additional information will be made available by our annual and quarterly reports and other filings that we make from time to time with the SEC. These forward-looking statements speak only as of the date of this press release. Factors or events that could cause our actual results to differ may emerge from time to time, and it is not possible for us to predict all of them. We undertake no obligation to update any forward-looking statement, whether as a result of new information, future developments or otherwise, except as may be required by applicable law.

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TransMedics Group, Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net revenue	$ 5,370	$ 7,091	$ 20,594	$ 18,012
Cost of revenue	1,597	2,053	6,421	6,205
Gross profit	3,773	5,038	14,173	11,807

Gross Margin	70%	71%	69%	66%
Operating expenses:				
Research, development and clinical trials	5,163	4,155	15,990	14,283
Selling, general and administrative	10,335	5,493	26,283	18,012
Total operating expenses	15,498	9,648	42,273	32,295
Loss from operations	(11,725)	(4,610)	(28,100)	(20,488)
Other income (expense):				
Interest expense	(979)	(971)	(2,896)	(3,014)
Other income (expense), net	(249)	499	(532)	1,087
Total other expense, net	(1,228)	(472)	(3,428)	(1,927)
Loss before income taxes	(12,953)	(5,082)	(31,528)	(22,415)
Provision for income taxes	(9)	(6)	(19)	(22)
Net loss	$ (12,962)	$ (5,088)	$ (31,547)	$ (22,437)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.47)	$ (0.19)	$ (1.14)	$ (0.94)
Weighted average common shares outstanding, basic and diluted	27,701,252	27,156,135	27,564,589	23,885,517

* Reconciliation of Gross to Net revenue for certain payments made to customers (in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Gross revenue from sales to customers	$ 5,413	$ 7,973	$ 21,717	$ 20,139
Less: clinical trial payments reducing revenue	43	882	1,123	2,127
Total net revenue	$ 5,370	$ 7,091	$ 20,594	$ 18,012

TransMedics Group, Inc.
CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands)
(unaudited)

	September 30, 2021	December 31, 2020
Current assets:		
Cash and cash equivalents	$ 22,495	$ 24,581
Marketable securities	80,360	101,061
Accounts receivable	4,150	6,864
Inventory	14,869	11,934
Prepaid expenses and other current assets	3,703	2,326
Total current assets	125,577	146,766
Property and equipment, net	5,063	4,754
Restricted cash and other long-term assets	506	506
Total assets	$ 131,146	$ 152,026
Current liabilities:		
Accounts payable	$ 2,682	$ 1,206
Accrued expenses and other current liabilities	12,769	10,317
Deferred revenue	320	263
Current portion of deferred rent	152	93
Total current liabilities	15,923	11,879
Long-term debt, net of discount	35,058	34,657
Deferred rent, net of current portion	1,616	1,599
Total liabilities	52,597	48,135
Total stockholders' equity	78,549	103,891
Total liabilities and stockholders' equity	$ 131,146	$ 152,026

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