

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 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): November 4, 2020

TransMedics Group, Inc.

(Exact Name of Registrant as Specified in Charter)

Massachusetts
(State or Other Jurisdiction of Incorporation)

001-38891
(Commission File Number)

83-2181531
(I.R.S. Employer Identification No.)

200 Minuteman Road
Andover, Massachusetts 01810
(Address of Principal Executive Offices, and Zip Code)

(978) 552-0900
Registrant's Telephone Number, Including Area Code

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 communication 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 communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, no par value per share	TMDX	The Nasdaq Stock Market LLC (The Nasdaq Global Market)

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 November 4, 2020, TransMedics Group, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended September 30, 2020. A copy of this press release is furnished as Exhibit 99.1 and is incorporated herein by reference.

The information in this Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any filing by the Company, under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press release issued by TransMedics Group, Inc. on November 4, 2020

SIGNATURE

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.

TRANSMEDICS GROUP, INC.

Date: November 4, 2020

By: /s/ Stephen Gordon

Name: Stephen Gordon

Title: Chief Financial Officer, Treasurer and Secretary



TransMedics Reports Third Quarter 2020 Financial Results

Andover, Mass. – November 4, 2020 – 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, 2020.

Recent Highlights

- Net revenue of \$7.1 million in the third quarter of 2020, representing a 2% decrease compared to the third quarter of 2019
- Completed enrollment in OCS Heart DCD U.S. clinical program
- Received FDA approval for OCS Heart DCD continued access protocol

“Our sequential growth in the third quarter was driven by the ongoing recovery in transplant activities in the United States in addition to the rapid enrollment and completion of our OCS Heart DCD U.S. trial,” said Waleed Hassanein, MD, President and Chief Executive Officer. “We are actively engaged with FDA to complete the review of the additional OCS Heart EXPAND CAP data and the rescheduling of our OCS Heart FDA Advisory Committee meeting. We remain confident in our ability to have all three of our OCS products approved and commercially available in the second half of 2021.”

Third Quarter 2020 Financial Results

Net revenue for the third quarter of 2020 was \$7.1 million, a 2% decrease compared to \$7.2 million in the third quarter of 2019. The slight decrease in revenue was predominantly a result of the lingering impact of the global COVID-19 pandemic through the third quarter.

Gross margin for the third quarter of 2020 was 71% as compared to 59% in the third quarter of 2019.

Operating expenses for the third quarter of 2020 were \$9.6 million compared to \$11.5 million in the third quarter of 2019. The decrease in operating expenses was due primarily to our cash preservation measures enacted earlier this year in response to the COVID-19 pandemic.

Net loss for the third quarter of 2020 was \$5.1 million compared to \$8.3 million in the third quarter of 2019.

Cash, cash equivalents and marketable securities were \$132.7 million as of September 30, 2020.

2020 Financial Outlook

As previously announced, TransMedics is not providing annual guidance for 2020 due to the unpredictability of the duration and the magnitude of the impact of the COVID-19 pandemic.

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 Wednesday, November 4, 2020. Investors interested in listening to the conference call may do so by dialing (833) 378-1026 for domestic callers or (236) 712-2344 for international callers, followed by Conference ID: 1716957. 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 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; 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; 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 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; and the risks identified under the heading “Risk Factors” and elsewhere in our annual report on Form 10-K for the year ended December 28, 2019 and our quarterly report on Form 10-Q for the quarter ended June 30, 2020, which is available on the SEC’s website at www.sec.gov. 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 (except as otherwise noted) 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.

Investor Contact:

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TransMedics Group, Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands)

	<u>Fiscal Three Months Ended</u>		<u>Fiscal Nine Months Ended</u>	
	<u>September 30, 2020</u>	<u>September 28, 2019</u>	<u>September 30, 2020</u>	<u>September 28, 2019</u>
Net revenue	\$ 7,091	\$ 7,205	\$ 18,012	\$ 17,547
Cost of revenue	2,053	2,989	6,205	7,425
Gross profit	5,038	4,216	11,807	10,122
Gross Margin	71%	59%	66%	58%
Operating expenses:				
Research, development and clinical trials	4,155	4,939	14,283	13,608
Selling, general and administrative	5,493	6,519	18,012	17,423
Total operating expenses	9,648	11,458	32,295	31,031
Loss from operations	(4,610)	(7,242)	(20,488)	(20,909)
Other income (expense):				
Interest expense	(971)	(1,084)	(3,014)	(3,290)
Change in fair value of preferred stock warrant liability	—	—	—	(341)
Other income (expense), net	499	56	1,087	200
Total other expense, net	(472)	(1,028)	(1,927)	(3,431)
Loss before income taxes	(5,082)	(8,270)	(22,415)	(24,340)
Provision for income taxes	(6)	(10)	(22)	(30)
Net loss	\$ (5,088)	\$ (8,280)	\$ (22,437)	\$ (24,370)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.19)	\$ (0.39)	\$ (0.94)	\$ (2.05)
Weighted average common shares outstanding, basic and diluted	27,156,135	21,131,618	23,885,517	11,882,626

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

	<u>Fiscal Three Months Ended</u>		<u>Fiscal Nine Months Ended</u>	
	<u>September 30, 2020</u>	<u>September 28, 2019</u>	<u>September 30, 2020</u>	<u>September 28, 2019</u>
Gross revenue from sales to customers	\$ 7,973	\$ 7,876	\$ 20,139	\$ 19,381
Less: clinical trial payments reducing revenue	882	671	2,127	1,834
Total net revenue	\$ 7,091	\$ 7,205	\$ 18,012	\$ 17,547

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

	<u>September 30, 2020</u>	<u>December 28, 2019</u>
Current assets:		
Cash and cash equivalents	\$ 21,397	\$ 20,092
Marketable securities	111,317	60,596
Accounts receivable	6,141	6,559
Inventory	12,984	11,216
Prepaid expenses and other current assets	2,287	1,538
Total current assets	<u>154,126</u>	<u>100,001</u>
Property and equipment, net	4,690	4,792
Restricted cash and other long-term assets	506	506
Total assets	<u>\$ 159,322</u>	<u>\$ 105,299</u>
Current liabilities:		
Accounts payable	\$ 778	\$ 7,247
Accrued expenses and other current liabilities	11,474	8,332
Deferred revenue	1,347	166
Current portion of deferred rent	25	370
Total current liabilities	<u>13,624</u>	<u>16,115</u>
Long-term debt, net of discount	34,525	34,146
Deferred rent, net of current portion	1,623	389
Total liabilities	<u>49,772</u>	<u>50,650</u>
Total stockholders' equity	<u>109,550</u>	<u>54,649</u>
Total liabilities and stockholders' equity	<u>\$ 159,322</u>	<u>\$ 105,299</u>