

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): June 11, 2019

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 June 11, 2019, TransMedics Group, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the first quarter ended March 30, 2019. 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 June 11, 2019

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: June 11, 2019

By: /s/ Stephen Gordon

Name: Stephen Gordon

Title: Chief Financial Officer, Treasurer and Secretary



TransMedics Reports First Quarter 2019 Financial Results

Andover, Mass. – June 11, 2019 – 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 March 30, 2019.

Recent Highlights

- Recorded net revenue of \$4.7 million in the first quarter of 2019, representing 86% growth compared to the first quarter of 2018
- Received FDA approval for expanded indications of the Organ Care System (OCS™) Lung to include donor lungs initially deemed unacceptable for transplantation which includes unutilized donor lungs after donor brain death (DBD) and donor circulatory death (DCD)
- Final results of the OCS Heart EXPAND Trial and long-term follow-up data of the OCS Lung EXPAND Trial were presented at the 39th Annual Meeting and Scientific Sessions of the International Society for Heart and Lung Transplantation in April 2019
- Received IDE approval for the U.S. OCS Heart DCD clinical trial, which will enable DCD heart transplant procedures to be performed in the U.S. for the first time
- Completed initial public offering of approximately 6.5 million shares, raising approximately \$97.4 million in net proceeds, after deducting underwriting discounts and commissions

“TransMedics is committed to expanding access to life-saving transplant procedures for patients suffering from end-stage organ failure across multiple disease states using our paradigm-shifting OCS platform. We are pleased with our first quarter results, which demonstrated meaningful progress in sales growth, and expansion of our body of clinical evidence for our lung and heart transplant indications. Our recent FDA PMA approval significantly expands our commercial opportunity in the U.S. by enabling the use of currently unutilized DBD and DCD donor lungs for transplantation,” said Waleed Hassanein, M.D., President and Chief Executive Officer.

First Quarter 2019 Financial Results

Net revenue for the first quarter of 2019 was \$4.7 million, an 86% increase compared to \$2.5 million in the first quarter of 2018. The increase in net revenue was primarily driven by commercial sales of OCS Lung products in the U.S. as well as OCS Liver disposable sets for clinical trial use.

Gross margin for the first quarter of 2019 was 55% as compared to 37% in the first quarter of 2018. The increase in gross margin was primarily driven by the increase in net revenue from

sales of OCS disposable sets, higher average selling prices, and improved efficiency in production.

Operating expenses for the first quarter of 2019 were \$8.5 million compared to \$5.7 million in the first quarter of 2018. The increase in operating expenses was primarily driven by expenses associated with supporting commercial sales of our OCS Lung in the United States, our preparation to operate as a public company, and spending associated with clinical trial activity.

Net loss for the first quarter of 2019 was \$6.9 million compared to \$4.9 million in the first quarter of 2018.

Cash and cash equivalents were \$12.2 million as of March 30, 2019. In May 2019, TransMedics completed an initial public offering, raising approximately \$97.4 million of net proceeds, after deducting underwriting discounts and commissions.

2019 Financial Outlook

TransMedics projects net revenue for the full-year 2019 to be in the range of \$23.5 million to \$25.5 million, which represents 81% to 96% 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, June 11, 2019. Investors interested in listening to the conference call may do so by dialing (866) 221-1172 for domestic callers or (270) 215-9603 for international callers, followed by Conference ID: 2475974. 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 ex-vivo 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. Investors are cautioned not to place undue reliance on these forward-looking statements, including statements about our results of operations, commercial opportunity and the adoption and benefits of the OCS. Each forward-looking statement is subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied in such statement. Applicable risks and

uncertainties include those related to our anticipation that we will continue to incur losses in the future; our potential 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, 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; 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 expectations for 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 estimates regarding revenues, expenses and needs for additional financing; and the risks identified under the heading “Risk Factors” and elsewhere in the final prospectus dated May 1, 2019 related to our initial public offering, which is available on the SEC’s website at www.sec.gov. Additional information will be made available by our quarterly reports on Form 10-Q 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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646-924-1769

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TransMedics Group, Inc.
CONDENSED CONSOLIDATED STATEMENT OF OPERATIONS
(in thousands)
(unaudited)

	Fiscal Three Months Ended	
	March 30, 2019	March 31, 2018
Net revenue*	\$ 4,676	\$ 2,519
Cost of revenue	2,103	1,595
Gross profit	<u>2,573</u>	<u>924</u>
Gross Margin	55%	37%
Operating expenses:		
Research, development and clinical trials	3,882	3,465
Selling, general and administrative	4,653	2,240
Total operating expenses	<u>8,535</u>	<u>5,705</u>
Loss from operations	<u>(5,962)</u>	<u>(4,781)</u>
Other income (expense):		
Interest expense	(1,093)	(258)
Change in fair value of preferred stock warrant liability	273	(30)
Other (expense) income, net	(103)	175
Total other expense, net	<u>(923)</u>	<u>(113)</u>
Loss before income taxes	<u>(6,885)</u>	<u>(4,894)</u>
Provision for income taxes	(10)	(7)
Net loss	<u>\$ (6,895)</u>	<u>\$ (4,901)</u>

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

	Fiscal Three Months Ended	
	March 30, 2019	March 31, 2018
Gross revenue from sales to customers	\$ 5,290	\$ 2,756
Less: clinical trial payments reducing revenue	(614)	(237)
Total Net Revenue	<u>\$ 4,676</u>	<u>\$ 2,519</u>

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

	<u>March 30,</u> <u>2019</u>	<u>December 29,</u> <u>2018</u>
Current assets:		
Cash and cash equivalents	\$ 12,215	\$ 20,241
Accounts receivable	5,146	3,438
Inventory	11,294	9,277
Prepaid expenses and other current assets	1,404	1,838
Total current assets	<u>30,059</u>	<u>34,794</u>
Property and equipment, net	3,750	3,474
Deferred offering costs	4,444	3,383
Restricted cash and other long-term assets	506	506
Total Assets	<u>\$ 38,759</u>	<u>\$ 42,157</u>
Current liabilities:		
Accounts payable	\$ 5,499	\$ 4,720
Accrued expenses and other current liabilities	9,989	7,178
Deferred revenue	359	306
Current portion of deferred rent	354	349
Total current liabilities	<u>16,201</u>	<u>12,553</u>
Preferred stock warrant liability	625	898
Long-term debt, net of discount	33,785	33,670
Deferred rent, net of current portion	667	759
Total liabilities	<u>51,278</u>	<u>47,880</u>
Total Preferred Stock and Stockholder's Equity (Deficit)	<u>(12,519)</u>	<u>(5,723)</u>
Total Liabilities and Equity	<u>\$ 38,759</u>	<u>\$ 42,157</u>