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 3, 2019

TransMedics Group, Inc.
(Exact Name of Registrant as Specified in Charter)

Massachusetts	**001-38891**	**83-2181531**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 7.01. Regulation FD Disclosure.

On June 3, 2019, TransMedics Group, Inc. ("the Company") issued a press release announcing the receipt of the pre-market approval from the U.S. Food and Drug Administration for the Company's Organ Care System Lung to expand the indication for use to include a larger pool of donor lungs that are currently seldomly utilized for transplantation due to limitations of cold storage. A copy of the 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 in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filling.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by TransMedics Group, Inc. on June 3, 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 4, 2019

By: /s/ Stephen Gordon
Name: Stephen Gordon
Title: Chief Financial Officer, Treasurer and Secretary

Exhibit 99.1

TransMedics Announces the Second FDA PMA Approval for its OCS Lung System, Allowing Access to a Larger Pool of Donor Lungs that are Currently Seldomly Utilized for Transplantation Due to Limitations of Cold Storage

Andover, Mass. – June 3, 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 announced that it has received an FDA PMA approval for expanded clinical indications of the Organ Care System (OCS) Lung. This approval will enable the OCS Lung System to be used for the preservation and ex-vivo assessment of both standard criteria donor lungs as well as the larger pool of donor lungs initially deemed unacceptable for procurement and transplantation based on limitations of cold static preservation. This approval will also enable the OCS Lung System to be used with both donors after brain death (DBD) and donors after circulatory death (DCD). Prior to this latest FDA approval, the OCS Lung System was approved for standard criteria lungs from DBD donors only. Based on this FDA PMA approval, TransMedics will expand its post-market Thoracic Organ Perfusion (TOP) Registry to collect long-term post-market data from recipients of all OCS Lung preserved standard criteria and initially deemed unacceptable donor lungs.

"We are pleased with the FDA approval which uniquely positions the OCS Lung System as the only technology approved for both standard criteria and initially deemed unacceptable donor lungs for transplantation," said Dr. Waleed Hassanein, CEO of TransMedics, Inc. "With this approval, the OCS Lung System could enable a significant increase in donor lung utilization for transplantation in the U.S. from those DBD and DCD donors that were initially deemed unacceptable based on limitations of cold storage. Now, these lungs can be preserved and assessed ex-vivo using our OCS Lung System to determine their suitability for transplantation. This marks a major milestone forward in our drive to expand access to life-saving transplant procedures for patients suffering from end-stage organ failure," said Dr. Hassanein.

"Lung transplant surgeons now have access to a technology that enables preservation and assessment and use of lungs from a wide range of donors. Importantly, the OCS Lung System enables these capabilities from the minute the donor lungs are procured until they are ready to be transplanted into the recipient across wide distances," said Dr. Gabriel Loor, the U.S. Principal Investigators for the OCS Lung EXPAND trial. "This important milestone offers the promise to further expand the number and improve the quality of donor organs for sick patients waiting for lung transplant worldwide," said Prof. Dirk Van Raemdonck the International Principal Investigator for the OCS Lung EXPAND Trial.

The FDA approval is based on the results of the OCS Lung EXPAND pivotal international, multicenter trial that demonstrated safety and effectiveness of TransMedics' OCS Lung System for ex-vivo preservation and assessment of donor lungs from DBD and DCD donors that were initially deemed unacceptable for procurement and for transplantation due to the limitations of cold static preservation.

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 the implications of the PMA approvals and potential market for TransMedics products. 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 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 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; our use of proceeds from our initial public offering; 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.

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