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): September 7, 2021

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 (§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 7.01 Regulation FD Disclosure.

On September 7, 2021, TransMedics Group, Inc. issued a press release announcing the receipt of the pre-market approval from the U.S. Food and Drug Administration for the Company's OCS Heart System for donors after brain death indication. A copy of this press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01 (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 filing.

Cautionary Note Regarding Forward-Looking Statements. The press release attached as Exhibit 99.1 hereto contains forward-looking statements that involve certain risks and uncertainties that could cause actual results to differ materially from those expressed or implied by these statements. Please refer to the cautionary notes in the press release regarding these forward-looking statements.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by TransMedics Group, Inc. on September 7, 2021
104	The cover page from this Current Report on Form 8-K of TransMedics Group, Inc., formatted in Inline XBRL

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: September 7, 2021

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

Exhibit 99.1

TransMedics, Inc Press Release | Sept 7, 2021

TransMedics Receives FDA Approval for its OCS Heart System Enabling Broader Utilization of Donor Hearts for Transplantation in the U.S.

Andover, Mass. – September 7, 2021 – 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 the U.S. Food and Drug Administration (FDA) has granted premarket approval (PMA) of its OCS Heart System for use with organs from donors after brain death (DBD).

The OCS Heart System is indicated for the preservation of DBD donor hearts deemed unsuitable for procurement and transplantation at initial evaluation due to limitations of prolonged cold static cardioplegic preservation (e.g., > 4 hours of cross-clamp time). This indication is based on the results of the OCS Heart EXPAND Trial, the associated OCS Heart EXPAND Continued Access Protocol (CAP) and the OCS Heart PROCEED II Trial.

"We are thrilled to achieve this important milestone for heart transplantation in the United States. This was the culmination of several years of collaboration with leading heart transplant experts and FDA to bring our lifesaving OCS technology to help more heart transplant patients in the U.S.," said Waleed Hassanein, MD, President and Chief Executive Officer. "We are honored and humbled that the OCS Heart System is now the only FDA approved device indicated for ex-vivo perfusion and assessment of both donor hearts and lungs as an alternative to the antiquated cold storage preservation. We take this responsibility very seriously, and we are looking forward to the next phase of commercial activities, the initiation of the OCS Heart Perfusion (OHP) Registry, and potentially expanding our clinical indications in the future."

"The approval of this revolutionary technology marks a critical step forward for heart transplantation," said Dr. Jacob Schroder, surgical director of heart transplantation at Duke University Medical Center and the principal investigator for the OCS Heart EXPAND Trial. "The OCS Heart System allows surgeons to assess donor heart's viability in real time and minimizes the negative effects of cold storage. This will increase utilization of donor hearts that are rarely used due to limitations of cold storage preservation. By expanding the donor pool of acceptable hearts, the OCS will enable us to better meet the growing demand for heart transplantation in the U.S. and save lives."

The approval of the OCS Heart System follows FDA approval and subsequent commercialization of the OCS Lung System. TransMedics is also seeking FDA approval for its OCS Liver System, which received a favorable vote in support its approval by a panel of experts during an FDA Advisory Committee Meeting on July 14th, 2021.

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 future events, including the commercialization and market opportunity of the OCS Heart and potential regulatory approvals for our OCS Liver System. 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 and public payors of benefits offered by the OCS; the impact of the outbreak of the novel strain of coronavirus and associated containment, remediation and vaccination 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 timing of and our ability to commercialize and market our OCS products; 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; 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 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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