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): July 14, 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 July 14, 2021, TransMedics Group, Inc. issued a press release announcing an update with respect to the U.S. Food and Drug Administration Advisory Committee's meeting related to the Premarket Approval Application for the OCS Liver. 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 July 14, 2021

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: July 15, 2021

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

Exhibit 99.1

TransMedics Announces Positive FDA Advisory Committee Vote for the OCS Liver System

Panel votes unanimously in support of the OCS Liver System's safety and effectiveness

Andover, Mass. – July 14, 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, announced today that after review and discussion of TransMedics' clinical evidence from the OCS Liver PROTECT trial, the Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee convened by the U.S. Food and Drug Administration ("FDA") has issued a favorable vote in support of approval of the OCS Liver System.

The panel voted 14 to 0, that there is reasonable assurance that the OCS Liver System is effective and 14 to 0, that there is reasonable assurance of the OCS Liver System's safety. The panel voted 12 to 1, with 1 abstaining, that the benefits of the OCS Liver System outweigh its risks.

"This vote marks a key milestone as we move towards potential FDA approval of the OCS Liver technology, which stands to benefit U.S. patients with end-stage liver failure. We are looking forward to working collaboratively with the FDA to finalize the review of the OCS Liver PMA," said Dr. Waleed Hassanein, President and Chief Executive Officer. "I want to take this opportunity to thank the OCS Liver PROTECT Trial investigators, trial coordinators, patients who enrolled in the OCS Liver PROTECT Trial, and the TransMedics Liver team."

"The OCS Liver PROTECT Trial demonstrated that the OCS Liver has the ability to provide superior clinical outcomes and improve utilization of donor livers for transplantation. This is truly a game-changer in the field of liver transplantation," said Dr. James F. Markmann, Chief of the Division of Transplantation Surgery at Massachusetts General Hospital and the lead investigator of the OCS Liver PROTECT Trial. "The OCS Liver System allows surgeons to both assess and enhance donor liver function before transplantation, which can improve transplant safety and enables the use of donor livers that would otherwise go unused. If approved by the FDA, I believe the OCS Liver will allow us to provide more life-saving transplants for patients with end-stage liver disease."

"Today's FDA panel vote brings us closer to potentially having all three OCS products FDA approved and commercially available in the U.S. for lung, heart and liver transplantation," Dr. Waleed Hassanein concluded.

FDA Advisory Committees provide the FDA with independent opinions and nonbinding recommendations from outside medical experts. While the FDA will consider the opinions and recommendations expressed at the Advisory Committee, the FDA will make a decision regarding whether to approve the premarket approval application ("PMA") for the use of the OCS Liver System for transplantation after completion of its review of the PMA.

The OCS Lung System is approved in the U.S., and the OCS Heart System is currently under review by the FDA after receiving a positive vote by the FDA's Circulatory System Device Advisory Panel in April.

PROTECT Trial

The OCS Liver PROTECT trial met its primary effectiveness endpoint and demonstrated a significant reduction in early allograft dysfunction (EAD) with OCS (OCS 18% vs. Control 31%, p=0.009). OCS preserved livers also demonstrated a significant reduction in histopathological evidence of IR injury after reperfusion and significant attenuation of reperfusion syndrome in the recipient. OCS use was also associated with significant reduction in the incidence of ischemic biliary complications through one year, a leading cause of graft failure after liver transplant (OCS 2.6% vs. Control 9.9%, p=0.019). The OCS Liver System enabled ex-vivo liver allograft assessment, which resulted in a significantly higher utilization of livers from donors after cardiac death (DCD) (OCS 51% vs. Control 25%, p=0.007). PROTECT's safety endpoint was met with a low average number of liver graft-related serious adverse events (OCS 0.046 to Control 0.075, non-inferiority p<0.0001). Patient survival at one year was high at 94% for both OCS and Control arms.

About the OCS System

The OCS System is the only portable, multi-organ platform for donor lungs, hearts and livers for transplantation. The OCS System mimics the human body by providing donor organs with warm, oxygenated blood perfusion throughout preservation that maintains the organs in a living, functional state. The assessment capabilities of the OCS System enable diagnostic evaluation to allow for the analysis of organ function and viability prior to transplant. Normothermic perfusion on the OCS System optimizes the organ conditions and allows for therapeutic intervention through replenishing oxygen and nutrients.

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 those that affect 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 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 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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