

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): May 3, 2022

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 May 3, 2022, TransMedics Group, Inc. (the “Company”) issued a press release announcing the Company’s financial results for the quarter ended March 31, 2022. 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 May 3, 2022 |
| 104 | Cover Page Interactive Data File (embedded within the Inline XBRL document) |

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: May 3, 2022

By: /s/ Stephen Gordon

Name: Stephen Gordon

Title: Chief Financial Officer, Treasurer and Secretary



TransMedics Reports First Quarter 2022 Financial Results

Andover, Mass. - May 3, 2022 - 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 31, 2022.

Recent Highlights

- Net revenue of \$15.9 million in the first quarter of 2022, a 125% increase compared to the first quarter of 2021
- Received FDA pre-market approval (PMA) of OCS™ DCD heart indication on April 28, 2022
- Results from the U.S. randomized OCS™ DCD Heart trial along with OCS™ Lung Trial 5-year data presented at the International Society of Heart and Lung Transplantation (ISHLT) annual meeting

“We are proud of our strong first quarter revenue performance and are now laser focused on continuing to drive commercial growth across each of our three OCS technology platforms,” said Waleed Hassanein, MD, President, and Chief Executive Officer. “The National OCS™ Program (NOP) was our primary growth driver, providing us with a high level of confidence in our strategy and in our ability to enable sustained growth in transplant volumes to help more patients in need of life-saving organ transplant procedures.”

ISHLT 2022 Clinical Presentation Summary

Data from the U.S. randomized OCS™ DCD Heart trial presented at ISHLT 2022 showed that OCS™ Heart technology enabled successful utilization of 89% of DCD donor hearts. Results demonstrated 1- and 2-year survival rates of 93% in the DCD OCS™ treatment arm compared to 86% and 83% respectively in the DBD Control arm using standard criteria heart transplanted with cold storage.

OCS™ Lung EXPAND Trial 5-year data showed that the use of the OCS™ Lung with extended criteria DBD and DCD donor lungs resulted in a 5-year survival rate of 68%, compared to 59% for lung transplant survival outcomes in the U.S. reported by UNOS/OPTN national reports.

First Quarter 2022 Financial Results

Net revenue for the first quarter of 2022 was \$15.9 million, a 125% increase compared to \$7.1 million in the first quarter of 2021. The increase was due primarily to the continued increase in commercial sales of the OCS™ Heart and OCS™ Liver in the United States.

Gross margin for the first quarter of 2022 was 76%, as compared to 68% in the first quarter of 2021.

Operating expenses for the first quarter of 2022 were \$21.5 million, compared to \$11.3 million in the first quarter of 2021. The increase in operating expense was driven predominantly by increased investment in the company's NOP, our next generation OCS™ platform, as well as further investments in general commercial efforts and corporate infrastructure. First quarter operating expenses in 2022 included \$2.3 million of stock compensation expense, compared to \$1.1 million of stock compensation in the first quarter of 2021.

Net loss for the first quarter of 2022 was \$10.6 million, compared to \$7.9 million in the first quarter of 2021.

Cash, cash equivalents and marketable securities were \$72.0 million as of March 31, 2022.

2022 Financial Outlook

TransMedics is updating full year 2022 net revenue to be in the range of \$59 million to \$65 million, which represents 95% to 115% growth compared to the company's prior year net revenue. TransMedics' prior 2022 net revenue guidance was \$49 million to \$55 million.

Webcast and Conference Call Details

The TransMedics management team will host a conference call beginning at 5:00 p.m. ET / 2:00 p.m. PT on Tuesday, May 3, 2022. Investors interested in listening to the conference call may do so by dialing (844) 200-6205 for domestic callers or (929) 526-1599 for international callers, followed by Conference ID: 215877. 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 full year guidance, and statements about our operations and financial position, business plans and our ability to deliver OCS technology to more patients. 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 or refinance existing debt 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 ability to expand access to OCS through the National OCS Program; 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; our ability to 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; price increases of the components of our products; the timing or results of post-approval studies and any 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; the impact of the outbreak of COVID-19, including variants of the virus an associated containment, remediation and vaccination efforts; 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; 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 other factors that may be described in our filings with the Securities and Exchange Commission (the "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.

Investor Contact:

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TransMedics Group, Inc.
CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

| | Three Months Ended March 31, | |
|--|-------------------------------------|-------------|
| | 2022 | 2021 |
| Net revenue | \$ 15,880 | \$ 7,053 |
| Cost of revenue | 3,776 | 2,242 |
| Gross profit | 12,104 | 4,811 |
| Gross Margin | 76% | 68% |
| Operating expenses: | | |
| Research, development and clinical trials | 7,534 | 4,532 |
| Selling, general and administrative | 13,939 | 6,786 |
| Total operating expenses | 21,473 | 11,318 |
| Loss from operations | (9,369) | (6,507) |
| Other income (expense): | | |
| Interest expense | (960) | (952) |
| Other expense, net | (227) | (454) |
| Total other expense, net | (1,187) | (1,406) |
| Loss before income taxes | (10,556) | (7,913) |
| Provision for income taxes | (6) | (4) |
| Net loss | \$ (10,562) | \$ (7,917) |
| Net loss per share attributable to common stockholders, basic and diluted | \$ (0.38) | \$ (0.29) |
| Weighted average common shares outstanding, basic and diluted | 27,950,330 | 27,368,090 |

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

| | Three Months Ended March 31, | |
|--|-------------------------------------|-------------|
| | 2022 | 2021 |
| Gross revenue from sales to customers | \$ 15,880 | \$ 7,637 |
| Less: clinical trial payments reducing revenue | — | 584 |
| Total net revenue | \$ 15,880 | \$ 7,053 |

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

| | <u>March 31, 2022</u> | <u>December 31, 2021</u> |
|---|-----------------------|--------------------------|
| Current assets: | | |
| Cash and cash equivalents | \$ 17,897 | \$ 25,580 |
| Marketable securities | 54,104 | 66,872 |
| Accounts receivable | 11,724 | 5,934 |
| Inventory | 16,714 | 14,859 |
| Prepaid expenses and other current assets | 5,356 | 5,460 |
| Total current assets | 105,795 | 118,705 |
| Property and equipment, net | 12,044 | 9,841 |
| Operating lease right-of-use assets | 5,669 | 5,847 |
| Restricted cash | 500 | 500 |
| Total assets | <u>\$ 124,008</u> | <u>\$ 134,893</u> |
| Current liabilities: | | |
| Accounts payable | \$ 2,934 | \$ 6,651 |
| Accrued expenses and other current liabilities | 15,738 | 16,337 |
| Deferred revenue | 247 | 250 |
| Operating lease liabilities | 1,337 | — |
| Total current liabilities | 20,256 | 23,238 |
| Long-term debt, net of discount | 35,334 | 35,197 |
| Operating lease liabilities, net of current portion | 8,508 | 8,604 |
| Total liabilities | 64,098 | 67,039 |
| Total stockholders' equity | 59,910 | 67,854 |
| Total liabilities and stockholders' equity | <u>\$ 124,008</u> | <u>\$ 134,893</u> |