UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

___, Individually and on behalf of all others similarly situated, Plaintiff, v. TRANSMEDICS GROUP, INC., WALEED HASSANEIN, and STEPHEN GORDON, Defendants.	**Case No:** **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff __ ("Plaintiff"), individually and on behalf of all other persons similarly situated, by Plaintiff's undersigned attorneys, for Plaintiff's complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and information and belief as to all other matters, based upon, among other things, the investigation conducted by and through Plaintiff's attorneys, which included, among other things, a review of the Defendants' public documents, public filings, wire and press releases published by and regarding TransMedics Group, Inc. ("TransMedics" or the "Company"), and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

NATURE OF THE ACTION

1. This is a class action on behalf of persons or entities who purchased or otherwise acquired publicly traded TransMedics securities between February 28, 2023 and January 10, 2025, inclusive (the "Class Period"). Plaintiff seeks to recover compensable damages caused by

Defendants' violations of the federal securities laws under the Securities Exchange Act of 1934 (the "Exchange Act").

JURISDICTION AND VENUE

2. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

3. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331, and Section 27 of the Exchange Act (15 U.S.C. §78aa).

4. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)) as the alleged misstatements entered and the subsequent damages took place in this judicial district.

5. In connection with the acts, conduct and other wrongs alleged in this complaint, Defendants (defined below), directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mails, interstate telephone communications and the facilities of the national securities exchange.

PARTIES

6. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased TransMedics securities during the Class Period and was economically damaged thereby.

7. Defendant TransMedics describes itself as follows:

> The Company is a commercial-stage medical technology company transforming organ transplant therapy for end-stage organ failure patients across multiple disease states. The Company developed the Organ Care System ("OCS") to replace a decades-old standard of care. The OCS represents a paradigm shift that transforms organ preservation for transplantation from a static state to a dynamic environment that enables new capabilities, including organ optimization and assessment. The Company's OCS

technology replicates many aspects of the organ's natural living and functioning environment outside of the human body. The Company also developed its National OCS Program ("NOP"), an innovative turnkey solution to provide outsourced organ retrieval, OCS organ management and logistics services, to provide transplant programs in the United States with a more efficient process to procure donor organs with the OCS. The Company's logistics services include aviation transportation, ground transportation and other coordination activity.

8. Defendant TransMedics is incorporated in Massachusetts and its head office is located at 200 Minuteman Road, Andover, Massachusetts, 01810.

9. TransMedics's common stock trades on the NASDAQ under the ticker symbol "TMDX".

10. Defendant Waleed Hassanein, M.D. ("Hassanein") served as the Company's Chief Executive Officer ("CEO") and President at all relevant times. He also founded the Company.

11. Defendant Stephen Gordon ("Gordon") served as the Company's Chief Financial Officer ("CFO") at all relevant times.

12. Defendants Hassanein and Gordon are collectively referred to herein as the "Individual Defendants."

13. Each of the Individual Defendants:

(a) directly participated in the management of the Company;

(b) was directly involved in the day-to-day operations of the Company at the highest levels;

(c) was privy to confidential proprietary information concerning the Company and its business and operations;

(d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;

(e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;

(f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or

(g) approved or ratified these statements in violation of the federal securities laws.

14. TransMedics is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

15. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to TransMedics under *respondeat superior* and agency principles.

16. Defendant TransMedics and the Individual Defendants are collectively referred to herein as "Defendants."

SUBSTANTIVE ALLEGATIONS

Materially False and Misleading Statements Issued During the Class Period

17. On February 27, 2023, the Company filed with the SEC its annual report on Form 20-F for the period ending December 31, 2022 (the "2022 Annual Report"). Attached to the 2022 Annual Report were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Defendants Hassanein and Gordon attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting, and the disclosure of all fraud.

18. The 2022 Annual Report contained the following risk disclosure:

We depend heavily on the success of the OCS and its achieving market acceptance. If we are unable to successfully commercialize the OCS, our business may fail.

We have invested all of our efforts and financial resources in the development of the OCS, educating surgeons, transplant centers, Organ Procurement Organizations and private and public payors of the benefits of the OCS, providing services related to the OCS and launching our National OCS Program. Although we have received PMAs from the FDA for each of our three OCS products, we might not successfully commercialize the OCS for these approved indications or obtain approvals for additional indications or in additional jurisdictions on our planned timing or at all. Our ability to generate product revenue and become profitable depends primarily on sales of OCS Perfusion Sets and OCS Solutions, which we refer to collectively as disposable sets. Our assumptions regarding demographic trends, donor organ availability and the use of transplantation as a treatment for end-stage organ failure may prove to be incorrect.

We expect that we will need to continue to demonstrate to surgeons, transplant center program directors, Organ Procurement Organizations and private and public payors that the OCS potentially results in some or all of the following: improvements in post-transplant clinical outcomes, increases in the utilization of donor organs, expansion of the pool of potential donors and reduction in the total cost of care as compared to available alternatives.

Surgeons, transplant centers and private and public payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. The cost of the OCS significantly exceeds the cost of cold storage preservation. In addition, our international customers and some U.S. customers use a direct acquisition model pursuant to which transplant centers train their own teams for retrieval and organ management using the OCS rather than utilizing our National OCS Program. Surgeons may not be willing to undergo training to use the OCS, may decide the OCS is too complex to adopt without appropriate training and may choose not to use the OCS, which may limit the adoption of the OCS under the direct acquisition model. Based on these and other factors, transplant center program directors, Organ Procurement Organizations and private and public payors may decide that the benefits of the OCS do not outweigh its costs. In addition, adoption of the OCS may be constrained by the capacity of individual transplant centers to perform transplants due to factors such as the number of its surgeons trained on the use of the OCS. As a result, demand for the OCS could be materially lower than we expect it to be, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

19. The statement in ¶ 18 was materially false and misleading at the time it was made because it omitted, among other issues, that TransMedics depends on coercive business tactics to market its OCS.

20. The 2022 Annual Report contained the risk disclosure:

Our failure to compete effectively will harm our business and operating results.

A broad range of medical device, pharmaceutical and biotechnology companies offer products, procedures and therapies that have the potential to limit the demand for organ transplantation. Companies within this group vary depending on the type of organ. New therapies for COPD, which includes emphysema and chronic bronchitis, could limit the demand for lung transplants. Alternative products, procedures and therapies including ventricular assist devices, cardiac rhythm management products, total artificial hearts, and drug therapies for the heart and surgical procedures could limit demand for heart transplants. Improved treatments for chronic diseases or conditions affecting the liver as well as efforts to develop artificial livers could limit the need for liver transplants. If demand for organ transplants decreases, sales of the OCS and its components will suffer.

Other companies may develop technologies and products that result in improved patient outcomes or are safer, easier to use, less expensive or more readily accepted than the OCS. These products or technologies could make the OCS obsolete or noncompetitive and reduce demand for our OCS products. Many of these providers of alternative products, procedures and therapies have greater name recognition, significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and clearances and marketing and selling products than we do. Smaller and other early stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. Third parties may also compete with us in recruiting and retaining qualified medical, engineering and management personnel, establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to or necessary for our products or development programs or otherwise advantageous to our business. Our failure to compete effectively will harm our business and operating results.

21. The statement in ¶ 20 was materially false and misleading at the time it was made because it omitted that the Company relies on coercion, kickbacks, and fraudulent overbilling in order to be competitive.

22. The 2022 Annual Report contained the following risk disclosure:

Failure to maintain an ethical and inclusive corporate culture, or damage to our reputation, could have a material adverse effect on our business.

We strive to create a culture in which our employees act with integrity, treat each other with respect and consider themselves empowered to report suspected misconduct. Our ability to attract and retain a high-quality workforce depends upon our commitment to a diverse and inclusive environment, ***along with our perceived trustworthiness and***

ethics. Issues can arise in any number of circumstances, including employment-related offenses such as workplace harassment and discrimination, ***regulatory noncompliance***, failure to properly use and protect data and systems, and violations of our employee policies, as well as from actions taken by regulators or others in response to such conduct. Addressing allegations of misconduct detracts focus from business operations and is expensive. ***We have adopted policies to promote compliance with laws and regulations*** as well as to foster a respectful workplace for all employees. These policies, which include a code of business conduct and ethics, an insider trading policy, a Regulation FD policy, a sexual harassment policy, a regulated fraternization policy, and a whistleblower policy, are a component of our effort to minimize employee misconduct as well as activities that frequently result in allegations of misconduct, but our employees may fail to abide by these policies. ***In addition to damaging our reputation, actual or alleged misconduct could affect the confidence of our shareholders, regulators and other parties and could have a material adverse effect on our business, financial condition and operating results***.

(Emphasis added).

23. The statement in ¶ 22 was materially false and misleading at the time it was made because it omitted that the Company was already engaging in certain activities (among others, fraudulent overbilling, coercion, kickbacks in exchange for the use of deficient organs that reputable surgeons had rejected, and covering up safety issues) that, if publicly disclosed were likely to result in material harm to the Company's reputation, and regulatory scrutiny or action.

24. The 2022 Annual Report contained the following risk disclosure:

Even after approval for the OCS, we are subject to continuing regulation by regulatory authorities and entities in the United States and other countries, and if we fail to comply with any of these regulations, our business could suffer.

Even after approval of the OCS for a specific indication, we are subject to extensive continuing regulation by the FDA and other regulatory authorities and entities. We are subject to Medical Device Reporting regulations, which require us to report to the FDA if we become aware of information that reasonably suggests our product may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device we market would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health, and maintain records of other corrections or removals. The FDA closely regulates promotion and advertising and all claims that we make for the OCS. If the FDA determines that our promotional materials, training or advertising activities

constitute promotion of an unapproved use of the OCS, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement actions by the FDA or state agencies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- recall, suspension or termination of distribution, administrative detention, injunction or seizure of organ-specific OCS Consoles or disposable sets;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or for modifications to existing products, and refusing or delaying our requests for PMAs for new intended uses of the OCS;
- withdrawing or suspending PMA approvals that have already been granted, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any corrective action, whether voluntary or involuntary, as well as potentially defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

25. The statement in ¶ 24 was materially false and misleading at the time it was made because it understated the Company's risk regarding the OCS, considering that the Company actively took steps to cover up safety issues.

26. The 2022 Annual Report contained the following risk disclosure:

*If **we fail to maintain necessary FDA approvals for the OCS, or obtain necessary FDA approval for future uses of the OCS, we will not be able to commercially sell and market the OCS.***

The OCS products are medical devices subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. The FDA regulates the design, development, testing, manufacturing, labeling, selling, promoting, distributing, importing, exporting and shipping of the OCS. We have obtained a PMA for each of the OCS Lung, OCS Liver and OCS Heart for both DBD and DCD indications. We received

> 510(k) clearances for the OCS Lung Solution for cold flush, storage and transportation of donor lungs in July 2021, and for the OCS Lung Donor Flush Set in November 2022.
>
> PMA approval could be withdrawn or other restrictions imposed if post- market data demonstrate safety issues or inadequate performance. The FDA can also require removal of 510(k) cleared devices from the market in case of safety issues.
>
> If we are not able to maintain the necessary regulatory approvals for the OCS, or obtain the necessary regulatory approvals or clearances for future products on a timely basis or at all, our financial condition and results of operations would suffer, possibly materially, and our business might fail.

27. The statement in ¶ 26 was materially false and misleading at the time it was made because it understated the Company's risk regarding the OCS, considering that the Company actively took steps to cover up safety issues.

28. On February 27, 2024, the Company filed with the SEC its annual report on Form 20-F for the period ending December 31, 2023 (the "2023 Annual Report"). Attached to the 2023 Annual Report were certifications pursuant to SOX signed by Defendants Hassanein and Gordon attesting to the accuracy of financial reporting, the disclosure of any material changes to the Company's internal control over financial reporting, and the disclosure of all fraud.

29. The 2023 Annual Report contained the following risk disclosure:

> ***Our long-term growth depends on our ability to expand access to the OCS through our NOP.***
>
> We have developed the NOP, an innovative turnkey solution to provide outsourced organ retrieval and OCS organ management, to provide transplant programs with a more efficient process to procure donor organs with the OCS. We believe the NOP will continue to expand access and use of the OCS. However, we may not be successful in the continued development of our NOP, which will depend on recruiting, training and retaining qualified surgeons and pilots and establishing and maintaining effective coordination with transplant centers and regional Organ Procurement Organizations to locate donor organs and recipients. We may not be able to recruit, train and retain surgeons, pilots and other qualified personnel, including due to demand for their capabilities and competitive compensation offered by other employers. In order to recruit, train and retain such highly qualified employees, we also may need to increase

the level, or change the form or composition, of the compensation that we pay to them, which would increase our expenses.

In addition to our own surgical and clinical personnel, we utilize a network with a limited number of partners for organ retrieval, organ preservation and transportation services offered through our NOP. If any of these relationships are interrupted or terminated, or if one or more partners are unable or unwilling to fulfill their obligations for any reason, NOP services to our customers may be interrupted. We also may not be able to identify or negotiate with additional partners on terms that are commercially reasonable to us. The interruption or failure to retain or replace partners for our NOP would negatively impact our operations and financial results. Furthermore, the expenses incurred by us to customers who participate in our NOP are dependent on many different market dynamics, including the cost of fuel and other transportation costs. Additional expenses incurred by our NOP could adversely affect our business, gross margin, financial condition, operating results, cash flows and prospects.

(Emphasis added).

30. The statement in ¶ 29 was materially false and misleading because it omitted that the Company utilized, among other malfeasance, coercive business tactics and fraudulent overbilling.

31. The 2023 Annual Report contained the following risk disclosure:

We depend heavily on the success of the OCS and it gaining additional market acceptance. If we are unable to continue to successfully commercialize the OCS, our business may fail.

We have invested substantial efforts and financial resources in the development of the OCS, educating surgeons, transplant centers, Organ Procurement Organizations and private and public payors of the benefits of the OCS, providing services related to the OCS and launching our NOP. Although we have received PMAs from the FDA for each of our three OCS products, we might not be able to continue to successfully commercialize the OCS for these approved indications or obtain approvals for additional indications or in additional jurisdictions on our planned timing or at all. Our ability to generate product revenue and become profitable depends primarily on sales of OCS Perfusion Sets and OCS Solutions, which we refer to collectively as disposable sets. Our assumptions regarding demographic trends, donor organ availability and the use of transplantation as a treatment for end-stage organ failure may prove to be incorrect.

We expect that we will need to continue to demonstrate to surgeons, transplant center program directors, Organ Procurement Organizations and private and public payors that the OCS potentially results in some or all of the following: improvements in post-transplant clinical outcomes, increases in the utilization of donor organs, expansion of

the pool of potential donors and reduction in the total cost of care as compared to available alternatives.

Surgeons, transplant centers and private and public payors often are slow to adopt new products, technologies and treatment practices that require additional upfront costs and training. The cost of the OCS significantly exceeds the cost of cold storage preservation. In addition, our international customers and some U.S. customers use a direct acquisition model pursuant to which transplant centers train their own teams for retrieval and organ management using the OCS rather than utilizing our NOP. Surgeons may not be willing to undergo training to use the OCS, may decide the OCS is too complex to adopt without appropriate training and may choose not to use the OCS, which may limit the adoption of the OCS under the direct acquisition model. Based on these and other factors, transplant center program directors, Organ Procurement Organizations and private and public payors may decide that the benefits of the OCS do not outweigh its costs. In addition, adoption of the OCS may be constrained by the capacity of individual transplant centers to perform transplants due to factors such as the number of its surgeons trained on the use of the OCS. As a result, demand for the OCS could be materially lower than we expect it to be, which would materially and adversely affect our business, financial condition, operating results, cash flows and prospects.

32. The statement in ¶ 31 was materially false and misleading at the time it was made because it omitted, among other issues, that TransMedics depends on coercive business tactics to market its OCS.

33. The 2023 Annual Report contained the following risk disclosure:

Prior to our acquisitions to facilitate our aircraft operations, we had no experience operating aircraft ourselves, and we may not be able to achieve the anticipated benefits of our acquisitions or further expansion of our aircraft operations.

Prior to our acquisitions to facilitate our aircraft operations, we had no experience operating aircraft ourselves, and we depend on the management team of Summit and additional employees we may hire for the successful operation of aviation transportation services and the integration into our NOP services offering. The management teams must work together to comply with applicable laws and regulations and to manage our growing NOP logistics network. The operation of aircraft is a highly regulated activity and one that involves unique risks, including those described above, which we have not needed to manage previously. We may not successfully manage these risks or profitably utilize, integrate, operate, maintain and manage our newly acquired aircraft, employees and other aircraft operations.

If we fail to retain the existing management of Summit, or if we fail to successfully manage our aircraft operations or growing logistics network, our ability to realize the

anticipated benefits of the acquisition of Summit or expansion of our NOP may be adversely affected.

(Emphasis added).

34. The statement in ¶ 33 was materially false and misleading at the time it was made because it omitted that TransMedics overbilled customers through unnecessary aviation costs, including using multiple planes for transport when one would suffice.

35. The 2023 Annual Report contained the following statement:

Failure to maintain an ethical and inclusive corporate culture, or damage to our reputation, could have a material adverse effect on our business.

We strive to create a culture in which our employees act with integrity, treat each other with respect and consider themselves empowered to report suspected misconduct. Our ability to attract and retain a high-quality workforce depends upon our commitment to a diverse and inclusive environment, along with our perceived trustworthiness and ethics. Issues can arise in any number of circumstances, including employment-related offenses such as workplace harassment and discrimination, regulatory noncompliance, failure to properly use and protect data and systems, and violations of our employee policies, as well as from actions taken by regulators or others in response to such conduct. Addressing allegations of misconduct detracts focus from business operations and is expensive. We have adopted policies to promote compliance with laws and regulations as well as to foster a respectful workplace for all employees. These policies, which include a code of business conduct and ethics, an insider trading policy, a Regulation FD policy, a sexual harassment policy, a regulated fraternization policy, and a whistleblower policy, are a component of our effort to minimize employee misconduct as well as activities that frequently result in allegations of misconduct. We continuously assess our policies and provide training to our employees, but our employees may fail to abide by these policies. In addition to damaging our reputation, actual or alleged misconduct could affect the confidence of our shareholders, regulators and other parties and could have a material adverse effect on our business, financial condition and operating results.

36. The statement in ¶ 35 was materially false and misleading at the time it was made because it omitted that the Company was already engaging in certain activities (among others, fraudulent overbilling, coercion, kickbacks in exchange for the use of deficient organs that reputable surgeons had rejected, and covering up safety issues) that, if publicly disclosed

were likely to result in material harm to the Company's reputation, and regulatory scrutiny or action.

37. The 2023 Annual Report contained the following risk disclosure:

Even after approval for the OCS, we are subject to continuing regulation by regulatory authorities and entities in the United States and other countries, and if we fail to comply with any of these regulations, our business could suffer.

Even after approval of the OCS for a specific indication, we are subject to extensive continuing regulation by the FDA and other regulatory authorities and entities. We are subject to Medical Device Reporting regulations, which require us to report to the FDA if we become aware of information that reasonably suggests our product may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device we market would likely cause or contribute to a death or serious injury if the malfunction were to recur. We must report corrections and removals to the FDA where the correction or removal was initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA caused by the device that may present a risk to health, and maintain records of other corrections or removals. The FDA closely regulates promotion and advertising and all claims that we make for the OCS. If the FDA determines that our promotional materials, training or advertising activities constitute promotion of an unapproved use of the OCS, it could request that we cease or modify our training or promotional materials or subject us to regulatory enforcement actions.

The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement actions by the FDA or state agencies, which may include any of the following sanctions:

- untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties;
- recall, suspension or termination of distribution, administrative detention, injunction or seizure of organ-specific OCS Consoles or disposable sets;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for premarket approval of new products or for modifications to existing products, and refusing or delaying our requests for PMAs for new intended uses of the OCS;
- withdrawing or suspending PMA approvals that have already been granted, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

> Any corrective action, whether voluntary or involuntary, as well as potentially defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business, and may harm our reputation and financial results.

38. The statement in ¶ 37 was materially false and misleading at the time it was made because it understated the Company's risk regarding the OCS, considering that the Company actively took steps to cover up safety issues.

39. The 2023 Annual Report contained the following risk disclosure:

> ***If we fail to maintain necessary FDA approvals for the OCS, or obtain necessary FDA approval for future uses of the OCS, we will not be able to commercially sell and market the OCS.***
>
> The OCS products are medical devices subject to extensive regulation in the United States by the FDA and other federal, state and local authorities. The FDA regulates the design, development, testing, manufacturing, labeling, selling, promoting, distributing, importing, exporting and shipping of the OCS. We have obtained a PMA for each of the OCS Lung, OCS Liver and OCS Heart for both DBD and DCD indications. We received 510(k) clearances for the OCS Lung Solution for cold flush, storage and transportation of donor lungs in July 2021, for the OCS Lung Donor Flush Set in November 2022, and for the OCS Heart Leukocyte Reducing Filter in October 2023.
>
> PMA approval could be withdrawn or other restrictions imposed if post- market data demonstrate safety issues or inadequate performance. The FDA can also require removal of 510(k) cleared devices from the market in case of safety issues.
>
> If we are not able to maintain the necessary regulatory approvals for the OCS, or obtain the necessary regulatory approvals or clearances for future products on a timely basis or at all, our financial condition and results of operations would suffer, possibly materially, and our business might fail.

40. The statement in ¶ 39 was materially false and misleading at the time it was made because it understated the Company's risk regarding the OCS, considering that the Company actively took steps to cover up safety issues.

41. The statements contained in ¶¶ 18, 20, 22, 24, 26, 29, 31, 33, 35, 37, and 39 were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company's business, operations and prospects, which

were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) TransMedics used kickbacks, fraudulent overbilling, and coercive tactics to generate business and revenue; (2) TransMedics engaged in unsafe practices and hid safety issues and generally lacked safety oversight; (3) the foregoing subjected TransMedics to heightened risk of scrutiny and regulatory risk; and (4) as a result, Defendants' statements about its business, operations, and prospects, were materially false and misleading and/or lacked a reasonable basis at all relevant times.

THE TRUTH BEGINS TO EMERGE

42. On February 21, 2024, U.S. Representative Paul Gosar issued a letter accusing TransMedics of misconduct including misappropriating corporate resources. Rep. Gosar is on the House Committee on Oversight and Accountability. This letter was reported on by The Daily Caller during market hours on February 22, 2024. The article noted the following about Rep. Gosar's characterizations of TransMedics' pricing of use of the TransMedics Organ Care System (the "OCS"):

> After FDA approval [for the OCS] was achieved in 2021, TransMedics began to change the entirety of its business model[.] Almost immediately, the cost of the one-time, disposable cassette utilized to encompass the organ during transportation and perfusion increased from the initial $7,000 to greater than $60,000 per disposable cassette.

43. The article posted Rep. Gosar's letter, which stated the following:

> Once FDA approval was achieved, TransMedics began to change the entirety of its business model. Transplant centers that participated in the trial and previously purchased the equipment were then mandated by TransMedics to utilize the OCS no less than three to five times per month, or centers were forced to return the OCS machine without reimbursement of their upfront purchase capital. TransMedics informed these initial centers that if volumes were not maintained, they would not offer more cassettes for purchase. ***Almost immediately, the cost of the one-time disposable cassette utilized to encompass the organ during transportation and perfusion increased from the initial $7,000 to greater than $60,000 per disposable cassette***. Additionally, transplant centers would no longer receive training for their medical teams to utilize the device at their discretion. Instead, TransMedics created its own team of individuals as the sole source

for any initiation of the OCS device and labeled this the National OCS Program, or NOP. Transplant centers could no longer purchase the medical device, rather lease the device and request the necessary TransMedics personnel for any OCS heart, liver, or lung organ recovery. Costs for TransMedics surgical recovery are approximately $20,000 per request.

(Emphasis added).

44. Rep. Gosar's letter also stated the following:

What began as a promising medical equipment innovation and an opportunity to increase transplantation nationwide***, is now being held hostage by a public company that has lost its true north***. TransMedics is more driven by revenue generation, and continuous forced bundling of services than it is by the opportunity to decrease the patient transplant waitlist.

Transplant center administrators and surgeons are now forced to weight the fiscal responsibilities of the hundreds of thousands in increased transplant costs versus a simple decision to use the best available technology to support the organ care and ultimately patient outcomes. ***TransMedics is not a collaborative partner in transplantation as administrators continue to push back against its coercive tactics***. It seems that TransMedics is more dedicated to driving its profits at the unfortunate expense of the United States taxpayers and patients who need services the most.

(Emphasis added).

45. The Daily Caller published, in pertinent part, the following portions of Rep. Gosar's letter posing questions to TransMedics:

- Although it is well understood that the use of private aircraft is necessary to ensure that human organs reach their recipient in time, ***my staff has received allegations that TransMedics uses private aircraft for convenient transportation of their staff and equipment, where no such urgency exists***. Has TransMedics ever use private aircraft to transport staff and equipment ***without the purpose of transporting organs?***
- It has come to my attention that ***many transplant centers are uncomfortable asking Medicare for reimbursement due to the increased costs associated with use of the TransMedics NOP***, and the significantly more expensive aircraft deployed by TransMedics Aviation. At a recent investor conference, you noted these transplant centers were misguided in their attempts to save money for their hospitals and taxpayers, stating, in part: "we don't have a reimbursement issue, it's an educational responsibility for our commercial team to bring transplant administrators up to the level of knowledge they need to understand that all of the NOP charges are fully reimbursed, and just walk them through the process." Please provide all materials TransMedics provides transplant centers to "walk

them through the process," including how to maximize reimbursements through Medicare.

- We understand that TransMedics has made significant investments in new model aircraft and has placed pressure on their hospital customers to utilize their aircraft, ***despite protests from hospitals that TransMedics Aviation carries significantly higher costs than their current providers. Some transplant centers have reported being pressured to use TransMedics' captive aircraft, at nearly double the cost, or risk losing access to TransMedics' life saving device***. Has TransMedics ever denied a transplant center access to your life saving devices unless they use TransMedics' aircraft and pilots?

(Emphasis added).

46. On this news, the price of TransMedics stock fell $2.18 per share, or 2.5%, to close at $84.81 on February 22, 2024. The next day, it fell a further $1.67 per share, or 1.96%, to close at $83.14 per share on February 23, 2024.

47. The CEO denied Rep. Gosar's allegations in a letter dated February 26, 2024.

48. On January 10, 2025, Scorpion Capital issued a 300+ slide report about TransMedics (the "Report"). The Report was based on a "6-month investigation with over 30 interviews, including ex-employees, surgeons, leading transplant centers, organ procurement organizations, competitors, and its largest customers."

49. The Report accused TransMedics of, among other things, overbilling hospitals that use its services, effectively forcing customers to use certain services, and providing to patients organs that had been rejected by reputable physicians, by way of physicians who were paid by TransMedics. The Report also verified the substance of Rep. Gosar's claims.

50. The Report stated the following as an introduction about Scorpion Capital's conclusions:

> In 20 years of shorting, ***TransMedics is the most extreme and grotesque healthcare fraud we have encountered, not only for its scale, but because it is predicated on the exploitation of the most vulnerable patients – the terminally ill, desperate for an organ***. ***The "lucky" patients who receive a diseased, damaged organ rejected by reputable surgeons and centers*** – the type that TransMedics NOP service traffics in and flings off-

label onto its rig – or ones with dead, necrotic tissue after rotting on the device, ***are oblivious to the cesspool of perverse, secret incentives that steered the organ their way***. The corruption pervades every aspect of the business model. It is more accurately a racket, the closest we've seen in the public markets to a Mafia-style extortion scheme. Tony Soprano took pride in clever schemes that showcased his cunning and business acumen, like his Bust-Out Scheme, Esplanade Project, and Bogus Stock Scam – and stock scam is a fitting segue for us to note that any resemblance between real and fictional characters is purely accidental.

(Formatting altered from original).

51. The Report further stated the following:

Perverse incentives are central to understanding TransMedics [business model.] It exists solely as a creature of a preposterous Medicare reimbursement loophole unique to transplants – which regulators are racing to kill off, unbeknownst to bulls, taking TransMedics down with it. Private payor coverage is almost non-existent, as they're in on the joke. ***TransMedics is thus entirely a government pay scam – just like $10K toilet seats. Medicare reimburses transplant centers for all reasonable and necessary organ acquisition charges, which are rolled up into each center's Medicare Cost Report***. The rub: organ acquisition charges – which include TransMedics device and NOP fees - have no cap, as "reasonable" is undefined. An ex-TransMedics reimbursement executive detailed the nuances: "the structure – it's totally crazy…if they for pay for an OCS system on the NOP with the flight, all of these costs get paid at cost plus back to the hospital"; "Waleed will talk about it all the time…his investor calls…he will talk about how Medicare pays the cost…what are you guys worried about?"

(Formatting altered from original).

52. The Report referenced Rep. Gosar's letter and stated the following:

Our research indicates that not only are the CEO's denials [in the February 26, 2024 letter mentioned above] utterly false, ***but that the conduct detailed in Gosar's letter is far more serious than he is aware***. The allegations and key points in the letter were confirmed by numerous former employees, as well as by major transplant centers that we spoke to across 30+ interviews. We start with an ex-logistics manager who played a key role in managing TMDX's flight operations as part of the NOP, which he told us is "essentially like Amazon for organs." He began by saying that "in August 2023, we didn't have a single plane" and "wouldn't touch logistics" – "we would contract out" and "hire third parties," but that it all changed in a key moment when "a decision was made: we need to bring all the logistics in house." In a revealing moment, he stated TransMedics is not even really a medical device company: "instead of selling devices, we started selling a service."

(Formatting altered from original).

53. The Report further said the following about how TransMedics pressures centers to use its services:

> ***Centers are now forced to use the organ procurement service and TMDX aircraft, according to the ex-employee***, contradicting the CEO's denials: "they have to use our clinical service." He stated they no longer sell the devices in the US, but still do so abroad – a telling admission given the CEO's claims that TransMedics must operate the device for quality control: "we sell devices in other countries…in the US we no longer sell devices because it just doesn't make sense." Two former staff provided the same color. A reimbursement executive bluntly stated "yes, you do" when we asked if centers must use the NOP, and noted the switch was so heavy-handed that even centers who already bought and had devices on the shelf could no longer use them. An ex-organ procurement surgeon confirmed that "centers now are obliged to use their transportation service."
>
> (Formatting altered from original).

54. The Report further stated that "[t]ransplant surgeons at centers across the US corroborated that they are forced to use the TransMedics NOP service in order to access the device [the OCS]."

55. The Report also stated that the "NOP [National OCS Program] service is, in our opinion, a large-scale fraudulent billing racket, predicated on overcharging hospitals for unnecessary flights." It further stated:

> TransMedics' [NOP] is, we believe, a large-scale fraudulent billing conspiracy whereby customers – transplant centers and organ procurement organizations (OPO's) – are overcharged for its air transport service. Our investigation uncovered the details of how the scheme operates and how TransMedics ***allegedly tries to cover up its tracks, based upon interviews with former employees based at these hubs as well as transplant centers who conveyed their exasperation and outrage***. As background, its presentation indicates 17 hubs in major cities across the US where it stations devices, OCS specialists who are dispatched to operate the device, surgical procurement teams, and aircraft and flight crews.
>
> (Formatting altered from original).

56. The Report further stated:

> ***Ex-employees and hospitals described two key mechanisms of systematic billing fraud: 1) flying in non-local procurement teams by jet when a local team is already available***

> ***at its hub and could be driven, indicating the sole purpose was to exploit the customer via unnecessary air transport charges; 2) sending staff on multiple jets to the same location to further inflate the charge***. We begin with a former "OCS Specialist" who operated the device and worked in the Seattle hub, who we cloak as "Specialist #1." The specialist left recently because the practice was "just entirely unethical," beginning when the NOP was established: "it's a big reason why I decided to get out of the company"; "since they purchased aircraft, they were flying in nonlocal teams versus driving the local team." The specialist stated that over half of organ procurements were within driving distance – for example, the donor and recipient were both within Seattle -but TransMedics would still fly in nonlocal aircraft to run up the charge. In addition, the specialist indicated that "I would typically fly independently," meaning hospitals were billed for multiple aircraft for a single procurement with the device operator on one plane and surgical procurement staff arriving in others.
>
> (Formatting altered from original).

57. The Report stated the following about how Scorpion Capital believed the Company is dependent on unscrupulous surgeons, who receive kickbacks from TransMedics, for revenue:

> TransMedics revenue – and growth to date – is dependent on a handful of dubious physicians and centers, often of the same Egyptian or Middle East descent as the CEO and members of the leadership team – allegedly "prostitutes" who are "completely owned and operated by TransMedics," according to other surgeons we interviewed. ***We believe these high-volume OCS users a) receive what we think are inducements and kickbacks via stock, lavish travel, and other means; and b) we think that they are beneficiaries of high-risk organs that reputable surgeons won't touch, which we believe to be improperly steered their way as part of a quid pro quo that they arrive on an OCS pump***; and c) that they achieve these unusual volumes via vast off-label usage. A surgeon who runs a leading West Coast academic transplant center described a dynamic we see in almost every medtech or biotech fraud we short, when we asked if the CEO has a "little inner circle": "He does…Waleed's got people like that, that will stick by him because they're conflicted…they're making a lot of money consulting and speaking."
>
> (Formatting altered from original).

58. Scorpion Capital further stated its belief that "TransMedics is operating an organ trafficking scheme, shopping and steering rejected organs to its top users as a quid pro quo for accepting them on its device and via its NOP service." The Report further stated:

We conclude, based on extensive research, that TransMedics is engaging in a sinister scheme whereby organs are illegally steered to centers under the implicit or explicit quid pro quo that a) they accept the organ on its device and b) that it is transported via its NOP service on its private jets. The organ, we believe, therefore constitutes a kickback under the Anti-Kickback Statute ("Stark Law") and also, in our opinion, meets the legal definition of organ trafficking per the National Organ Transplant Act which makes it unlawful to "acquire, receive, or transfer any human organ for valuable consideration" – under penalty of fines and/or imprisonment; and per international conventions, such as the Istanbul Declaration and others.

(Formatting altered from original).

59. The Report provided the following detail on the mechanics of this scheme:

The full extent of the scheme became clear across interviews with ex-employees, transplant surgeons, and OPO's: ***TransMedics organ procurement team arrives for a retrieval; 2) the first center on the UNOS/OPTN transplant waiting list declines the organ, typically because it is old, defective, or otherwise compromised; 3) the organ is then classified as an "Expedited Offer," a loophole in the OPTN organ allocation system which is now routinely abused to bypass the waiting list and preferentially steer the organ; 4) TransMedics and/or OPO's with whom it conspires allegedly start "dialing for dollars," according to ex-employees and others, to offer the organ to centers willing to accept it with the understanding that it comes on a TransMedics pump and on its NOP aircraft*** – unsurprisingly, its highest-volume and most corrupt customers seem to get the call. OPTN instituted expedited placement rules in March 2021, with criteria to prevent a "jump ball" when the first center declines an organ – a well-meaning rule that backfired by providing an official pretext for rampant abuses.

(Formatting altered from original).

60. The Report further stated the following:

The NOP organ procurement service is "a ticking time bomb" staffed with imported H1B surgeons unlicensed to practice medicine in the US, from high-risk areas like India, Pakistan, and the Middle East; resulting in butchered and lost organs.

61. The Report stated the following about what an ex-TransMedics executive had told Scorpion Capital:

An ex-TransMedics Executive expressed shock at the incompetence of its retrieval surgeons, sharing a recent anecdote of a heart that was rejected after it was severed without enough aorta for transplant. The executive stated "it's really hard to get a procurement surgeon," so they've hired surgeons "that nobody wants to hire…these are people who need jobs"; "they weren't good enough to stay employed at a transplant

hospital" and do NOP recoveries as a last resort – "it's an order of magnitude of pain and more to work for TransMedics."

* * *

The executive provided names of particular NOP surgeons known for repeatedly making critical mistakes, suggesting they end up at TransMedics after running from something – "you're not a very good surgeon…a couple of deaths…two of their transplant surgeons…I heard repeatedly about their lack of skill from others." The executive provided the name of the surgeon who allegedly severed the aorta improperly: "I heard that from a reputable source…she got an unusable heart…it didn't have enough aorta to sew into the recipient…nobody in their right mind would hire her" – "I could tell you seven surgeons who should be excluded from surgery for life because they're very, very brutal…they have terrible outcome…they kill more patients than they save…and they still go on to jump around the country at various hospital…it happens a lot."

(Formatting altered from original).

62. Compounding on this issue, as well as providing damaged organs rejected by reputable surgeons, the Report stated that "[o]rgans on TransMedics devices are managed by inexperienced, high-risk technicians called OCS Specialists, who allegedly receive only a week of training prior to engaging in the practice of medicine, putting organs and recipients in jeopardy."

63. The Report further said the following:

As part of its National OCS Program (NOP), TransMedics pumps are operated by technicians called OCS Specialists who are patently incapable and unqualified to do so – with allegedly such little training, support, or relevant experience that a reasonable person may call it gross negligence and/or malfeasance – and with high turnover as they appear to quit from the mistakes, stress, and chaos from insufficient training. Transplant centers appear to be in the dark and may be alarmed at their liability for allowing them into their OR's, as the technicians appear to clearly exercise medical/clinical judgment and manage, monitor, and medicate organs for 24 to 40+ hours. Previously, TransMedics trained hospitals on the device but now they must use its technicians – as part of the scheme alleged by Congressman Gosar and others – a bait and switch after FDA approval when it "began to change the entirety of its business model" and ceased training centers.

(Formatting altered from original).

64. The Report revealed the following about TransMedics' industry reputation:

TransMedics practices have broadly antagonized the entire transplant field, past the point of no return and consistent with a company in the midst of a customer exodus and death spiral. The level of rage, venom, and expletives – toward its CEO and management team, in particular – is unlike anything we have ever heard. Across dozens of interviews with surgeons, transplant center administrators, and ex-executives/employees, the sentiment was universal. Notably, its highest volume users exhibited similar animus and signaled their intent to eliminate or sharply reduce use of the TransMedics device as soon as possible. We begin with a prominent KOL [key opinion leader] and Director of a leading academic transplant center – whose colorful language was representative. The KOL is well-published with a national reputation, participated in TransMedics trials, and knows the CEO well: "their company, from a corporate culture point of view, is dishonest….their claims are exaggerated"; I don't like Waleed or a lot of their upper management…he's doing the fake it til you make it thing…what a f[***]-face he is…he's so disingenuous."

(Formatting altered from original).

65. The Report further stated the following:

The surgeon commented on the alienation and backlash in the transplant community, and noted the CEO's allegedly reactive personality – a recurring theme of interviews which described "screaming" episodes: "the alienation, some of us really hate Waleed because we just think he's dishonest"; "he gets angry when people say, no, we're not getting reimbursed . . . it pisses him off . . . they always get angry at the meetings when people get up . . . they tried to force it down everyone's throat . . . ***this is ridiculous that you are forcing us to use your hired surgeon and aviation company . . . this hard sell, push down your throat approach to the surgical community*** . . . there are a lot of people they pissed off."

(Formatting altered from original).

66. The Report said the following about TransMedics' business tactics:

An administrator at a pre-eminent, high-volume center detailed a pattern of "ridiculous" air transport charges with no invoice transparency, which were not part of any contract – involving multiple aircraft sent for a single recovery, allegedly resulting in charges of several hundred thousand dollars. ***When the center delayed payment, the executive alleged that members of TransMedics management team – COO Tamer Khayal and OCS liver head Magdy Attia – attempted to pressure them for payment by holding a heart hostage from an ICU transplant patient*** – "I hate flying their team all over the [f***ing] country. I hate it. I hate paying for private jets . . . I don't know why we have to pay for all these ridiculous transportation invoices . . . they just started flying their teams and then sending us these invoices . . . there's very little transparency . . . we just get a piece of paper . . . it's just a number . . . they could have made it up."

* * *

The administrator stated that TransMedics then denied a heart to a status one patient, when payment for suspect invoices was not forthcoming. Given the severity of th allegation, we confirmed the details with a second source, an executive at an OPO who was privy to the situation. The administrator voiced outrage: "I cannot stand working with them . . . it feels like I'm talking to a used car salesman . . . we had a recent situation, where we had some A/R . . . they declined a heart transplant for one of our patients in the ICU . . . they refused to . . . get the heart for us . . . I could not believe it . . . I had to spend eight hours . . . trying to beg and plead with them to release the hold because we didn't want to miss an opportunity to get an organ for one of our patients . . . I was groveling . . . this person is in the ICU . . . they're going to die . . . they're status one . . . the sickest patient in need of an organ, and TransMedics made that call . . . it was their COO, Tamer Khayal, who is not a clinician . . . a used car salesman . . . [Magdy Attia] was part of the people threatening us."

(Formatting altered from original).

67. The Report stated the following about an "accelerating customer exodus":

Our research indicates that TransMedics is in the middle of an accelerating customer exodus. One transplant center after another indicated that 1) using TransMedics wipes out their margin on transplant cases; 2) that despite the company's claims to the contrary, Medicare provides only partial reimbursement to centers and that private payors offer none, forcing centers to eat the cost; 3) that alternatives are radically cheaper, whether NRP which is perhaps a mere 3 to 5% of the cost of an OCS case, or a tsunami of new entrants with cheaper, alternative perfusion storage devices; and 4) that they plan to imminently sharply reduce or entirely eliminate their usage – within the next few months or quarters – or have already done so. We began with a surgeon who highlighted a recent Duke University study that showed their contribution margin dropped by an astounding 60% per transplant case when they used TransMedics. The surgeon indicated "Waleed and his people got so angry at the Duke guy for bringing it up" and that Duke had to sharply reduce their usage" because they were taking such a bath."

(Formatting altered from original).

68. The Report further stated the following:

Part 12. TransMedics device has no value proposition. Even its largest customers admit it has no clinical benefit to organs, using it off-label strictly for "surgeon lifestyle" and scheduling convenience; ***or, we believe, in exchange for organs steered improperly***.

* * *

The TMDX bull case is that the OCS pump is a multi-organ platform for lung, heart, liver, with kidney in development, that revolutionizes transport, preservation, and monitoring. In reality, it is a one-trick pony in liver, with zero chance in kidney, the most widely transplanted organ by orders of magnitude; OCS lung, run by the CEO's sister, is a colossal failure; and OCS Heart is currently in freefall. ***That leaves only OCS Liver, a gimmick used not for any clinical benefit but for a) off-label use for scheduling; b) by questionable centers whom we believe receive kickbacks and organs in exchange for taking them on the device***. We cover each organ in turn – starting with the failure of OCS in Europe, the canary in the coal mine – proof that it exist in the US solely due to a Medicare loophole. The head of a large transplant center: "You should look at the European market . . . you know what market share TransMedics has in Europe? Zero because they understand that they don't have a shot at competing . . . there are so many competitors and options . . . they cost 20% of TransMedics."

(Formatting altered from original).

69. The Report further stated the following:

Ex-employees, surgeons, and OPO's indicate that TransMedics OCS devices are plagued by failures leading to the loss of a significant percentage of organs; that livers in particular are prone to becoming necrotic, essentially rotting on the device, with dead tissue and parts of livers falling off; ***that the issues are prevalent enough that customers question why there hasn't been an FDA recall***; and that TransMedics is allegedly ***engaged in a systematic cover-up by lying to physicians, failing to report device failures to the FDA as required, with the CEO allegedly pressuring employees to doctor safety reports***. We begin with an ex-employee in medical safety roles, who stated that "it was a pretty complex device, so many malfunctions…kinks so the fluids and the gas were not able to flow properly…between 5-7% of the time, they lose the organ because of a failure." The employee indicated a cover-up: "yeah, that was definitely the case…I participated in those investigations heavily…when it came to reporting, everything was done to basically not report as much as possible."

(Formatting altered from original).

70. In addition, the Report stated the following regarding management efforts to conceal issues:

When we asked if the CEO was the one pushing to conceal device/safety events, the ex-employee stated "yeah, yeah absolutely" and alleged "a lot of changes" to replace compliance-minded staff with more amenable ones – "***I was asked to consistently phrase stuff differently, especially safety… I had meetings with Waleed on multiple occasions, when he said I don't like what you wrote here . . . why don't we just try to rephrase it? . . . it went through cycles and cycles of editing until he was satisfied*** . . . when I was writing my narrative, ***he'd be like, well, you need to write here that this death is not device-related…he was, like, you have to write its not related to the device***

. . . I'm like, I cannot write this . . ." The ex-employee indicated similar practices with respect to safety data submitted to the FDA prior to approval: "***TransMedics data was always under scrutiny because of multiple violations . . . and warning letters . . . because the FDA was aware that they are not conducting themselves in the most honest manner***."

(Formatting altered from original).

71. The Report said the following about lack of safety oversight at TransMedics:

The ex-employee further stated that TransMedics has no safety function or even one person in such a role, and that the VP of Global Regulatory Affairs featured on its management team is just "***an ornament because she worked at the FDA before . . . she was never in the office . . . she was not really involved with anything . . . she had never been to Boston . . . she was living in Washington, [D.C.]… she was not really engaged with any of us…we didn't know where she was or what she was doing***." The ex-employee further alleged that ***TransMedics had only one person in a safety role but terminated the entire function: "I still talk to a few people at the company . . . they do not have a safety person . . . they haven't hired anyone*** . . . it was a one-person operation . . . doing all safety for all trials and devices." We conducted a brief LinkedIn search to check, which showed ~900 employees but none with a profile consistent with such a safety role; the search did indicate a handful of clinical and regulatory affairs employees, albeit without any detail suggesting that their roles encompassed safety.

(Formatting altered from original).

72. The Report further said the following:

A medical director at OrganOx – which markets a nearly identical FDA-approved normothermic perfusion pump – ***indicated the device problems were even more widespread at 10-20% of transplant cases: "one recurrent theme that I seem to be hearing about . . . is the reliability of these machines . . . while an organ is on a machine, things can go very, very wrong . . . I've seen maybe . . . 10-20% have some sort of issue*** . . . if we had to discard an organ due to a machine error, that gets reported full stop . . . [It takes] a very loud voice to do that . . . I don't know if TransMedics has that." The ex-TransMedics safety employee stated some centers stopped using the device due to such issue: "I don't think the patient outcomes were as good…they had actually one of the worst outcomes." Another ex-employee, an OCS device operator, confirmed that centers ceased using the device due to poor outcomes: "I heard a lot of complaints…they were worried about the outcomes…they were saying that something had gone wrong."

(Formatting altered from original).

73. On this news, the price of TransMedics stock fell $3.74 per share, or 5.15%, to close at $68.81 on January 10, 2025. On January 13, 2025, TransMedics stock fell a further $4.76 per share, or 6.9%, to close at $64.05.

74. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common shares, Plaintiff and other Class members have suffered significant losses and damages.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

75. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class consisting of all persons other than defendants who acquired TransMedics securities publicly traded on the NASDAQ during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of TransMedics, members of the Individual Defendants' immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

76. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, TransMedics securities were actively traded on NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds, if not thousands of members in the proposed Class.

77. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

78. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

79. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- whether the Exchange Act was violated by Defendants' acts as alleged herein;
- whether statements made by Defendants to the investing public during the Class Period misrepresented material facts about the business and financial condition of TransMedics;
- whether Defendants' public statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- whether the Defendants caused TransMedics to issue false and misleading filings during the Class Period;
- whether Defendants acted knowingly or recklessly in issuing false filings;
- whether the prices of TransMedics securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

80. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as

the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

81. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- TransMedics shares met the requirements for listing, and were listed and actively traded on NASDAQ, an efficient market;
- As a public issuer, TransMedics filed periodic public reports;
- TransMedics regularly communicated with public investors via established market communication mechanisms, including through the regular dissemination of press releases via major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services;
- TransMedics's securities were liquid and traded with moderate to heavy volume during the Class Period; and
- TransMedics was followed by a number of securities analysts employed by major brokerage firms who wrote reports that were widely distributed and publicly available.

82. Based on the foregoing, the market for TransMedics securities promptly digested current information regarding TransMedics from all publicly available sources and reflected such information in the prices of the shares, and Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

83. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information as detailed above.

COUNT I
For Violations of Section 10(b) And Rule 10b-5 Promulgated Thereunder
Against All Defendants

84. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

85. This Count is asserted against Defendants is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

86. During the Class Period, Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

87. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- employed devices, schemes and artifices to defraud;
- made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of TransMedics securities during the Class Period.

88. Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of TransMedics were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of TransMedics, their control over, and/or receipt and/or modification of TransMedics's allegedly materially misleading statements, and/or their associations with the Company which made them privy to confidential proprietary information concerning TransMedics, participated in the fraudulent scheme alleged herein.

89. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other TransMedics personnel to members of the investing public, including Plaintiff and the Class.

90. As a result of the foregoing, the market price of TransMedics securities was artificially inflated during the Class Period. In ignorance of the falsity of Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of TransMedics securities during the Class Period in purchasing TransMedics securities at prices that were artificially inflated as a result of Defendants' false and misleading statements.

91. Had Plaintiff and the other members of the Class been aware that the market price of TransMedics securities had been artificially and falsely inflated by Defendants' misleading statements and by the material adverse information which Defendants did not disclose, they would not have purchased TransMedics securities at the artificially inflated prices that they did, or at all.

92. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

93. By reason of the foregoing, Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchase of TransMedics securities during the Class Period.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

94. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

95. During the Class Period, the Individual Defendants participated in the operation and management of TransMedics, and conducted and participated, directly and indirectly, in the conduct of TransMedics's business affairs. Because of their senior positions, they knew the adverse non-public information about TransMedics's false financial statements.

96. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to TransMedics's financial condition and results of operations, and to correct promptly any public statements issued by TransMedics which had become materially false or misleading.

97. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which TransMedics disseminated in the marketplace during the Class Period concerning TransMedics's results of operations. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause TransMedics to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of TransMedics within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of TransMedics securities.

98. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by TransMedics.

PRAYER FOR RELIEF

WHEREFORE, plaintiff, on behalf of plaintiff and the Class, prays for judgment and relief as follows:

(a) declaring this action to be a proper class action, designating plaintiff as Lead Plaintiff and certifying plaintiff as a class representative under Rule 23 of the Federal Rules of Civil Procedure and designating plaintiff's counsel as Lead Counsel;

(b) awarding damages in favor of plaintiff and the other Class members against all defendants, jointly and severally, together with interest thereon;

awarding plaintiff and the Class reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) awarding plaintiff and other members of the Class such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated:

THE ROSEN LAW FIRM, P.A.

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