UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

PATRICK COLLINS, on Behalf of Himself and All Others Similarly Situated, Plaintiff, v. TRANSMEDICS GROUP, INC., WALEED HASSANEIN, and STEPHEN GORDON, Defendants.	Civil Action No. **CLASS ACTION COMPLAINT FOR VIOLATIONS OF FEDERAL SECURITIES LAWS** **JURY TRIAL DEMANDED**

Plaintiff Patrick Collins ("Plaintiff"), individually and on behalf of all others similarly situated, by and through his attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, his counsel's investigation, which includes, without limitation: (a) review and analysis of regulatory filings made by TransMedics Group, Inc. ("TransMedics" or the "Company"), with the U.S. Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by TransMedics; and (c) review of other publicly available information concerning TransMedics.

NATURE OF THE ACTION AND OVERVIEW

1. This is a federal securities class action on behalf of all persons and entities that purchased or otherwise acquired publicly traded TransMedics securities between February 28, 2023 and January 10, 2025, inclusive (the "Class Period"), against TransMedics and certain of its officers and executives, seeking to pursue remedies under Sections 10(b) and 20(a) of the

Securities Exchange Act of 1934 (the "Exchange Act") and SEC Rule 10b-5 promulgated thereunder.

2. TransMedics, a commercial-stage medical technology company, focuses on organ transplant therapies and associated services. TransMedics' main medical device is the Organ Care System ("OCS"), a device for the transportation, preservation, and assessment of organs (lung, heart, and liver) for transplants. TransMedics also operates its National OCS Program ("NOP"), an outsourced end-to-end service comprised of its own fleet of private jets, organ procurement surgeons, and device technicians, which allows the Company to transport donor organs via ground and aviation transportation to organ recipients. Throughout the Class Period, TransMedics touted continued, record-setting quarterly revenue growth.

3. Unbeknownst to investors, throughout the Class Period, TransMedics employed a slew of illegal, coercive, deceptive, and ultimately unsustainable business tactics and practices, including:

- As alleged by a member of the U.S. Congress, once TransMedics received FDA approval of its OCS device, it began an illegal, anticompetitive, and unsustainable tying offensive, forcing hospitals to use its NOP service, including TransMedics' airplanes, to maintain access to OCS, as well as increasing the price of OCS by nearly ten times;
- TransMedics' NOP service engages in systematic illegal and unsustainable billing fraud by overcharging transplant centers and organ procurement organizations for the Company's air transport service, including by flying in non-local organ procurement teams on TransMedics' jets when a local team is already available and sending staff on multiple jets to the same location to further inflate the charge;
- TransMedics' revenue is dependent on a cadre of specific physicians and transplant centers who (1) receive inducements and other unsustainable kickbacks from the Company for using its OCS and NOP service; (2) are improperly steered organs from TransMedics as part of an unsustainable quid-pro-quo arrangement; and (3) achieve high utilization of TransMedics' OCS via unsustainable off-label OCS use. These high-volume users are allegedly the target of multiple federal and state regulatory investigations;
- TransMedics' NOP organ procurement service is fundamentally unsustainable, as it is staffed with unqualified, imported surgeons on H-1B visas who are not licensed to

practice medicine in the United States, resulting in a significant percentage of organs being rendered unfit for transplants due to shoddy surgical procedures;

- TransMedics' NOP organ procurement service allegedly attempts to place unsafe and damaged organs, including by concealing adverse organ information;
- Organs on TransMedics' OCS device are managed by inexperienced technicians with inadequate training;
- TransMedics' coercive and deceptive business practices, including as detailed above, have broadly antagonized the transplant world and jeopardized the Company's ability to maintain existing customer relationships or gain new customers. As a result, large customers have reduced or eliminated using TransMedics or are in the process of doing so. New alternative devices or techniques for transplant organ retrieval and preservation are making it easier for customers to switch from TransMedics.

(collectively, "Illegal, Coercive, and Unsustainable Business Practices").

4. As a result of these practices, TransMedics' statements about, among other things, its business practices and revenue generation were materially false and misleading, and the Company lacked a reasonable basis to support its guidance that its revenue would continue to grow at record levels.

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

JURISDICTION AND VENUE

6. The claims asserted herein arise under 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).

7. 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).

8. 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)). Substantial acts in furtherance of the alleged fraud

or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company is incorporated, and its principal executive offices are located in this Judicial District.

9. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone and wire communications, and the facilities of a national securities exchange.

PARTIES

10. Plaintiff Patrick Collins, as set forth in the accompanying certification, incorporated by reference herein, purchased TransMedics securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

11. Defendant TransMedics is incorporated under the laws of Massachusetts with its principal executive offices in Andover, Massachusetts. TransMedics' securities trades on the NASDAQ under the ticker symbol "TMDX."

12. 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.

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

14. Defendants Hassanein and Gordon (together, the "Individual Defendants" and together with the Company, "Defendants") because of their positions with TransMedics, possessed the power and authority to control the contents of, among other things, TransMedics quarterly and

annual reports, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of TransMedics' reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions with the Company, and their access to material non-public information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false and misleading statements pleaded herein.

FALSE AND MISLEADING STATEMENTS

15. On February 27, 2023, the start of the Class Period, TransMedics released its Form 10-K, filed with the SEC, reporting fourth quarter 2022 and full year 2022 financial results (the "2022 Annual Report"). The 2022 Annual Report contained the following risk disclosure:

> ***Our financial results may fluctuate from quarter to quarter, which makes our results difficult to predict and may cause our results to fall short of expectations.***
>
> Our financial results may fluctuate from quarter to quarter due to a number of factors, including the availability of donor organs for transplantation, which is unpredictable and could impact the volume of transplant procedures performed at transplant centers using the OCS and demand for our National OCS Program. Our revenue from sales may fluctuate significantly from quarter to quarter, and our future quarterly and annual expenses as a percentage of our revenue may be significantly different from those we have recorded in the past. Our financial results in some quarters may fall below expectations. Comparing our financial results on a period-to-period basis may not be meaningful, and you should not rely on our past results as an indication of our future performance. ***Because the timing of organ transplant procedures is generally unpredictable, we have not experienced seasonality in our business from quarter to quarter***.

[Emphasis added.]

16. The 2022 Annual Report also contained the following risk disclosure, in relevant part:

> ***We depend heavily on the success of the OCS and it 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.

[Emphasis added.]

17. Additionally, the 2022 Annual Report contained the following risk disclosure, in relevant part:

> ***We depend on third parties to transport donor organs and medical personnel for our National OCS Program, and limited availability of, or increases in the cost of, transportation could limit our ability to expand or operate our National OCS Program.***
>
> Our NOP depends on the use of a third-party network of private aircraft to transport medical personnel to retrieve donor organs and deliver donor organs to patients for transplantation. Reliance on private aircraft is subject to various risks, including those associated with change in fuel prices, work stoppages and weather-related operating hazards. In particular, private aircraft are occasionally in high demand and/or subject to price fluctuations based on market conditions. Further, availability is constrained by a limited number of private aircraft available in the United States and a limited number of qualified pilots. As a result, third party private aircraft providers may not be able to prioritize our use of their services.
>
> If we are unable to obtain flight services for our NOP when needed, we may be unable to utilize our NOP to satisfy demand. We also may be required to seek alternative and, potentially more costly, flight services. These flight costs represent a significant part of the cost structure for our NOP, and although the cost of flights is paid by our customers, a substantial increase in the cost of flight services, due to prolonged increases in fuel prices, lack of availability of aircraft or otherwise, may

> require us to incur additional costs to identify and obtain alternative flights or rebalance our inventory by shipping products to locations for which flight costs are less expensive or from which flights are more readily available, and customers may be unwilling or unable to incur higher costs of flights and therefore forgo use of our services and products for the retrieval of donor organs despite availability. Further, the capacity of our NOP is limited by the number of aircraft and pilots available for our use and as we continue to expand our NOP, we will be required to obtain access to a greater number of available aircraft and pilots.

18. The statements in ¶¶15-17 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

19. The 2022 Annual Report contained the following 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.

20. The statements in ¶19 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

21. 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.]

22. The statements in ¶21 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

23. 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.

24. The statements in ¶23 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

25. 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.
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> 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.
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> 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.

26. The statements in ¶25 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

27. Attached to the 2022 Annual Report were certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") signed by Hassanein and Gordon attesting to, among other things, 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.

28. On May 1, 2023, the Company released on Form 10-Q, filed with the SEC, its financial results for first quarter 2023. During the associated earnings call the same day, a securities analyst asked Hassanein whether TransMedics was "taking away share from cold storage? Or do you think the overall [market] is increasing?" In response, Hassanein stated TransMedics was simultaneously taking market share while increasing the size of the market. Specifically, Hassanein stated, in relevant part:

> We're taking a significant portion of the existing market, and we're growing the overall market. And again, the numbers speak for themselves. We've seen heart grew by 9% last year, lung grew by 7%, liver grew by 3%. We expect the overall growth of these organs to be higher in 2022 -- I'm sorry, 2023. And we're taking a meaningful percentage of their current volume. Why? Because we're streamlining the process through the NOP. And this is what I said earlier to Cecilia's question. Our strategy is not just to cannibalize the existing market. Our strategy is to do that plus grow the overall market. And I think our -- I believe that our results speak for themselves. We have demonstrated our ability to do both in our 2022 results, and we are continuing to see that trajectory in '23, and we expect that to continue going forward.

29. The statements in ¶¶27-28 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

30. On September 11, 2023, TransMedics presented at the Morgan Stanley 21st Annual Global Healthcare Conference 2023. During the presentation, Hassanein touted the Company's use of its own planes—as opposed to those owned by third parties—as a benefit to TransMedics customers because it reduced costs and improved margins. Specifically, Hassanein stated, in relevant part:

> [W]e wouldn't invest in this if we don't believe in what I'm going to say right now. For us, we get the aviation and the logistics business set up, right. From our perspective, it's game set and match because every transplant program does not want to be dealing with 17 vendors around aviation. They do not want to be dealing

> with multiple calls about different quotes from different operators. They do not want to deal with 3 to 4 margin stack up on top of the actual cost of the case.
>
> They know who TransMedics is. They trust what TransMedics is doing. They trust the quality of care and the quality of service we provide. And for us to provide the aviation services and the logistics, it would be -- again, we're no longer competing in the market with organ preservation technologies. We are in a league of our own called organ supply and that nobody else is in that space . . . .

31. The statements in ¶30 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

32. On November 6, 2023, the Company released on Form 10-Q, filed with the SEC, its financial results for third quarter 2023. During the associated earnings call the same day, Hassanein assured investors that the headwinds that the Company experienced to its margin in the third quarter of 2023 were temporary and would improve over the next few quarters. Specifically, Hassanein stated, in relevant part:

> Before I move on from logistics and aviation, let me share our expectations on our gross margin progression going forward. In 3Q, the inefficiencies associated with integrating Summit and streamlining the entire operation to focus on transplant was a bit of a headwind on our service margin. We expect this to improve over the next few quarters.
>
> Let me be crystal clear. We fully expect both our product and service margins to improve over the next several quarters as we gain more operational leverage and efficiency. Simply stated, 3Q margins do not, I repeat, do not represent our long-term margins at all. The expected inefficiencies of integration -- simply stated, 3Q margins do not represent our long-term margins at all, given the expected inefficiencies of integration and transitioning of the Summit operations.

33. The statements in ¶32 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

34. During the same call, a securities analyst asked for color on TransMedics' visibility and metrics related to the use of aviation to transport organs. In response, Hassanein assured investors that all costs were fully reimbursed. Specifically, Hassanein stated, in relevant part:

> This is not a question. This is a fact of organ transplant. Old aviation and logistics transport are fully reimbursed through the same mechanism of organ acquisition. There's no limit per se. In fact, we are doing this because we believe we could be more efficient and pass some of the efficiencies back to the transplant program.
>
> So I do not want anybody on this call to think that the aviation business is not reimbursed through normal mechanisms of organ transplant. There is no limit. There is no specifics. If the center feels that it's too expensive, they would ask for another [quote] or get from another vendor. But it's fully reimbursed. It's not a question of reimbursement. It's a question of making sure that we have the fleet, the efficiencies, the support team to be able to cover the missions.

35. The statements in ¶34 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

36. On February 27, 2024, the Company filed with the SEC its annual report on Form 10-K 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.

37. 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.

38. The statements in ¶¶36-37 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

39. 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 posttransplant 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.

40. The statements in ¶39 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

41. 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.

42. The statements in ¶41 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

43. The 2023 Annual Report contained the following statements:

> ***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.

44. The statements in ¶43 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

45. 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.

46. The statements in ¶45 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

47. 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.

48. The statements in ¶47 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and

Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

49. The 2023 Annual Report also contained the following risk disclosure:

> Our financial results may fluctuate from quarter to quarter, which makes our results difficult to predict and may cause our results to fall short of expectations.
>
> Our financial results may fluctuate from quarter to quarter due to a number of factors, including the availability of donor organs for transplantation, which is unpredictable and could impact the volume of transplant procedures performed at transplant centers using the OCS and demand for our NOP. Our revenue from sales may fluctuate significantly from quarter to quarter, and our future quarterly and annual expenses as a percentage of our revenue may be significantly different from those we have recorded in the past. In addition, the timing of acquiring additional aircraft for our aviation transportation services is uncertain and the amount we incur for such acquisitions is likely to differ from quarter to quarter. Our financial results in some quarters may fall below expectations. Comparing our financial results on a period-to-period basis may not be meaningful, and past results may not be an indication of our future performance. Because the timing of organ transplant procedures is generally unpredictable, we have not experienced seasonality in our business from quarter to quarter.

50. The statements in ¶49 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

51. On April 30, 2024, the Company released on Form 10-Q, filed with the SEC, its financial results for first quarter 2024. During the associated earnings call the same day, Hassanein and Gordon assured investors they had factored into guidance potential seasonality and other operational challenges they expected during the upcoming quarter. Specifically, Hassanein stated, in relevant part:

> I think we always are cognizant of what potential operational challenges in front of us. For example, we are very proud to have operating 14 planes hopefully in Q2. But we know that in the second half of the year, we have some of these planes are due for some annual service. So they're not going to be accessible to us. So we factored that into the guidance. We also factored in some of the -- any potential

> seasonality from summer vacations coming up for the holidays. So we always are prudent. When it comes to guidance, we want to -- when we issue guidance, we take it very seriously. So that's layered into our expectations here.

52. Specifically, Gordon stated, in relevant part:

> And Allen, I would just say, look, we don't expect a down quarter sequentially. We expect modest growth quarter-over-quarter. And that's the way we've modeled it, and I would expect that's the way we'll come in.

53. The statements in ¶¶51-52 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

54. On July 31, 2024, the Company released on Form 10-Q, filed with the SEC, its financial results for the second quarter of 2024. During the associated earnings call the same day, a securities analyst asked, "why shouldn't you be able to outperform that given you're already at more planes relative to what you had in the first half of the year by a pretty significant margin?" In response, Hassanein assured investors the Company would not "decelerate" and that there would be no surprises that would impact margin. Specifically, Hassanein stated, in relevant part:

> Listen, we do not expect to decelerate. We never do. However, what we always try to do with our guidance is to be practical and realistic, so there are no surprises whatsoever. Yes, we are at a higher number of operating aircraft, but we all know that when we buy an airplane, it doesn't go into service right away. It takes 6 to 8 weeks minimum to get operational. Yes, we doubled our crew size, but it takes some 6 to 8 weeks to be fully trained and operational. So there are some operational variabilities that we are factoring in our guidance. That's at least my perspective. And we take guidance very seriously, as you know. And we have tendency to be conservative to avoid any surprises.

55. The statements in ¶54 were materially false and misleading at the time they were made because they omitted, among other issues, that TransMedics relied on Illegal, Coercive, and Unsustainable Business Practices that, if publicly disclosed, were likely to materially harm the Company's business and reputation, and result in regulatory scrutiny or action.

56. The statements contained in ¶¶15-55 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 illegal, anticompetitive, and coercive business practices, such as kickbacks, billing fraud, and overcharging patients, which caused customers to stop using TransMedics' services and made it difficult for TransMedics to gain new customers; (2) TransMedics' NOP program relied on unsafe, unsustainable, and dangerous practices, which caused customers to stop using TransMedics' services and made it difficult for TransMedics to gain new customers; (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 EMERGES

57. 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.

58. 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.]

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

- 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.]

60. 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.

61. However, the price of TransMedics' shares remained inflated because the full truth of the Company's operations and the undisclosed risks to the Company resulting from these practices, as detailed herein, remained undisclosed and/or extant. Moreover, Defendants reassured the market by making further false and/or misleading statements and by denying the allegations in Rep. Gosar's letter, as described immediately below.

62. TransMedics' CEO, Defendant Hassanein, denied Rep. Gosar's allegations in a letter dated February 26, 2024. Among other things, Defendant Hassanein and TransMedics denied that (i) the Company increased the cost of its OCS product following FDA approval; (ii) it prohibited hospitals from training their personnel on OCS; and (iii) customers were forced to use TransMedics' NOP services as a condition of using OCS.

63. On October 28, 2024, after market hours, TransMedics issued a press release on Form 8-K filed with the SEC, announcing its financial results for third quarter 2024. During the associated earnings call the same day, the Company announced it had suffered a sequential decline in revenues and gross margin, representing the Company's first sequential revenue decline since third quarter 2021. Specifically, Gordon stated, in relevant part:

> For the third quarter of 2024, our total revenue was $108.8 million. This is an increase of 64% from the third quarter of 2023 and a 5% sequential decline from last quarter. In the U.S., transplant revenue was $104.9 million. U.S. revenue increased 76% from the third quarter of 2023 and was down 3% sequentially from last quarter.

* * *

> For the third quarter of 2024, our gross margin was 56%. This was down from 61% in the third quarter of 2023. In comparison to Q3 last year, this reflects the higher service component of our business . . . On the service side, margin was 19%, a decline from Q2 of '24.

64. Hassanein attributed the decline in revenue to the national decline in U.S. organ transplants during the quarter. Specifically, Hassanein stated, in relevant part:

> From a revenue perspective, we continue to deliver significant year-over-year growth, particularly in the U.S., offset by an overall U.S. transplant volume headwinds as well as routine scheduled aircraft maintenance, which we discussed on our last call.

* * *

> In Q3, overall U.S. national liver and heart transplant volumes declined sequentially approximately 5%, while total lung volumes declined by approximately 3% in the U.S. There is no clear reason for these declines other than normal variability of donor availability and potential summer seasonality. So the sequential decline in the U.S. case volume was directly in line with the decline in national transplant volumes.

65. Gordon attributed the margin erosion to, among other things, unscheduled maintenance of certain planes, the use of third parties to deliver organs, and the acquisition of new planes. Specifically, Gordon stated, in relevant part:

> For the third quarter of 2024, our gross margin was 56%. This was down from 61% in the third quarter of 2023 . . . On the service side, margin was 19%, a decline from Q2 of '24. And this was driven by several factors.
>
> First, similar to last quarter, we are spending ahead in clinical services and logistics as we prepare for future growth. There were three areas of spend to highlight. We are investing in pilots and pilot training to prepare for additional utilization of our owned planes in the coming quarters. Second, as Waleed mentioned, we have initial expenses related to our new aviation maintenance hub. And third, we have made additional investments in our NOP hubs, again preparing for required future demand. All in, this represents approximately $2 million of nonrecurring costs, and we also saw higher reliance on third-party logistics partners to cover NOP cases, which also had a negative impact on service margin.

66. TransMedics' disappointing results, including a sequential decline in revenues and gross margin, partially disclosed to the market that TransMedics' unsustainable business practices were no longer able to generate the financial results that TransMedics had achieved in prior reporting periods and/or represented a partial materialization of the undisclosed risks occasioned by TransMedics' unsustainable business practices, as detailed herein.

67. Specifically, TransMedics' decreasing NOP margins were due, in part, to (1) investing in pilots and pilot training to prepare for additional utilization of TransMedics-owned planes in the coming quarters; and (2) initial expenses related to TransMedics' new aviation maintenance hub. These expenses were a necessary partial materialization of the undisclosed risk of TransMedics' unsustainable business practices described above, including forcing hospitals to use its NOP service, including TransMedics' airplanes, to maintain access to OCS, and overcharging transplant centers and organ procurement organizations for the Company's air transport service.

68. In addition, TransMedics' claims that "overall U.S. national liver and heart transplant volumes declined sequentially approximately 5%, while total lung volumes declined by approximately 3%" ignored that TransMedics was no longer growing its transplant revenue in excess of national transplant growth and thus was losing market share.

69. Moreover, in its response to Rep. Gosar's letter, TransMedics claimed that its OCS device and NOP services "unequivocally led to a 12% increase in liver and heart transplantation in the US in 2023." If that is correct, the fact that transplants decreased in the third quarter 2024 demonstrated that TransMedics' unsustainable business practices were no longer effective in achieving increased successful organ transplants and that the Company's ability to grow the organ transplant market through its unsustainable business practices had ceased.

70. On this news, the price of TransMedics stock fell $37.74 per share, or nearly 30%, from $126.24 on October 28, 2024, to close at $88.50 on October 29, 2024.

71. However, the price of TransMedics' shares remained inflated because the full truth of the Company's operations and the undisclosed risks to the Company resulting from these practices, as detailed herein, remained undisclosed and/or extant.

72. On December 2, 2024, after market hours, TransMedics issued a press release on Form 8-K filed with the SEC, stating, among other things, that it was reducing its full year 2024 revenue guidance from between $425 million and $445 million to between $428 million and $432 million. The press release also announced that TransMedics' CFO, Defendant Gordon, would be replaced effective immediately.

73. TransMedics' reduction of its 2024 revenue guidance and the termination of its CFO partially disclosed to the market that TransMedics' unsustainable business practices were no longer able to generate the financial results that TransMedics had achieved in prior reporting periods and/or represented a partial materialization of the undisclosed risks occasioned by TransMedics' unsustainable business practices, as detailed herein.

74. On this news, the price of TransMedics stock fell $13.70 per share, or nearly 16%, from $85.14 on December 2, 2024, to close at $71.44 on December 3, 2024.

75. However, the price of TransMedics' shares remained inflated because the full truth of the Company's operations and the undisclosed risks to the Company resulting from these practices, as detailed herein, remained undisclosed and/or extant.

76. 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."

77. The Report accused TransMedics of, among other things, overbilling hospitals that use its services, effectively forcing customers to use certain services, and providing to patient's 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.

78. 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.

[Emphasis added].

79. 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?"
>
> [Emphasis edited from original.]

80. 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."
>
> [Emphasis edited from original.]

81. 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]."

82. 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.
>
> [Emphasis edited from original.]

83. 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.
>
> [Emphasis edited from original.]

84. 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."
>
> [Emphasis edited from original.]

85. 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.
>
> [Emphasis edited from original.]

86. 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.
>
> [Emphasis edited from original.]

87. 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.

88. 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."
>
> [Emphasis edited from original.]

89. 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."

90. 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.
>
> [Emphasis edited from original.]

91. 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."

[Emphasis edited from original.]

92. 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."

[Emphasis edited from original.]

93. 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."

94. 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."

[Emphasis edited from original.]

95. 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."

[Emphasis edited from original.]

96. 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."
>
> [Emphasis edited from original.]

97. 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 exemployee 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.***"
>
> [Emphasis edited from original.]

98. 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 exemployee 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.
>
> [Emphasis edited from original.]

99. 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."
>
> [Emphasis edited from original.]

100. 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.

101. 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.

CLASS ACTION ALLEGATIONS

102. 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 and entities that purchased or otherwise acquired publicly traded TransMedics securities between February 28, 2023, and

January 10, 2025, inclusive, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

103. 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 the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of TransMedics securities were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by TransMedics or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

104. 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.

105. 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.

106. 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:

(a) whether the federal securities laws were violated by Defendants' actions as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of TransMedics; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

107. 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 makes 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.

UNDISCLOSED ADVERSE FACTS

108. The market for TransMedics' securities were open, well-developed, and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures to disclose, TransMedics' securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class, relying upon the integrity of the market price of the Company's securities and market information relating to TransMedics, purchased or otherwise acquired publicly traded TransMedics' securities and have been damaged thereby.

109. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of TransMedics' securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about TransMedics' business, operations, and prospects as alleged herein.

110. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about TransMedics' financial well-being and prospects. These material misstatements and/or omissions had the effect of creating, in the market, an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

111. Defendants' wrongful conduct, as alleged herein, directly, and proximately caused the economic loss suffered by Plaintiff and the Class.

112. During the Class Period, Plaintiff and the Class purchased TransMedics' securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

113. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or 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 federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding TransMedics, their control over, and/or receipt and/or modification of TransMedics' allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning TransMedics, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE
(FRAUD-ON-THE-MARKET DOCTRINE)

114. The market for TransMedics' securities was open, well-developed, and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, TransMedics' securities traded at artificially inflated prices during the Class Period. On August 27, 2024, the Company's share price closed at a Class Period-high of $176.11 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's publicly traded securities relying upon the integrity of the market price of TransMedics' securities and market information relating to TransMedics and have been damaged thereby.

115. During the Class Period, the artificial inflation of TransMedics' securities was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made, a series of materially false and/or misleading statements about TransMedics' business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of TransMedics and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the

Company's securities. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

116. At all relevant times, the market for TransMedics' securities was an efficient market for the following reasons, among others:

(a) TransMedics securities met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market.

(b) As a regulated issuer, TransMedics filed periodic public reports with the SEC and/or the NASDAQ.

(c) TransMedics regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) TransMedics was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

117. As a result of the foregoing, the market for TransMedics' securities promptly digested current information regarding TransMedics from all publicly available sources and reflected such information in TransMedics' securities price. Under these circumstances, all purchasers of TransMedics' securities during the Class Period suffered similar injury through their purchase of TransMedics' securities at artificially inflated prices and a presumption of reliance applies.

118. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

119. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading,

and/or the forward-looking statement was authorized or approved by an executive officer of TransMedics who knew that the statement was false when made.

FIRST CLAIM
Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder
Against All Defendants

120. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

121. During the Class Period, Defendants carried out a plan, scheme, and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase TransMedics' securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, and each defendant, took the actions set forth herein.

122. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for TransMedics' securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein, or as controlling persons as alleged below.

123. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or of the mails and wires, engaged and participated in a continuous course of conduct to conceal adverse material information about TransMedics' financial well-being and prospects, as specified herein.

124. Defendants employed devices, schemes, and artifices to defraud, while in possession of material adverse nonpublic information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of TransMedics' value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about TransMedics and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

125. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development, and reporting of the Company's internal budgets, plans, projections, and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports, and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

126. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein or acted with reckless disregard for the truth in that they failed to

ascertain and to disclose such facts, even though such facts were available to them. Such Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing TransMedics' financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

127. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of TransMedics' securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trades, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired TransMedics' securities during the Class Period at artificially high prices and were damaged thereby.

128. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that TransMedics was experiencing, which were not disclosed by Defendants, Plaintiff and other

members of the Class would not have purchased or otherwise acquired their publicly traded TransMedics securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

129. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

130. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM
Violation of Section 20(a) of the Exchange Act
Against the Individual Defendants

131. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

132. Individual Defendants acted as controlling persons of TransMedics within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

133. In particular, Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

134. As set forth above, TransMedics and Individual Defendants each violated Section 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.