UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PLAINTIFF, Individually and on Behalf of All Others Similarly Situated, Plaintiff, vs. OUTSET MEDICAL, INC., LESLIE TRIGG, NABEEL AHMED, and REBECCA CHAMBERS, Defendants.	Case No.: **CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS** **DEMAND FOR JURY TRIAL**

Plaintiff, by and through its attorneys, alleges the following upon information and belief, except as to allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief are based upon, among other things, its counsel's investigation, which includes, without limitation: (a) review and analysis of public filings made by Outset Medical, Inc. ("Outset Medical" or the "Company") with the U.S. Securities and Exchange Commission (the "SEC"); (b) review and analysis of press releases and other publications disseminated by Defendants (defined below) and other parties; (c) review of news articles, shareholder communications, conference calls, and postings on Outset Medical's website concerning the Company's public statements; and (d) review of other publicly available information concerning the Company and the Individual Defendants (defined below).

NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all persons or entities who purchased Outset Medical common stock between September 15, 2020, and June 13, 2022, inclusive (the "Class Period") against Outset Medical and certain of its officers (collectively "Defendants") seeking to pursue remedies under the Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.* (the "Exchange Act").

2. Outset Medical is a medical technology company focused on kidney dialysis, the primary treatment for acute and chronic kidney failure. The Company's flagship product is the Tablo Hemodialysis System ("Tablo"). Tablo is a dialysis machine that purifies tap water and then artificially purifies and removes toxins from the blood of patients suffering from kidney failure.

3. Throughout the Class Period, Outset Medical touted that Tablo can "serve as a dialysis clinic on wheels" that had been "cleared by the [U.S.] Food and Drug Administration [(the "FDA")] for use in the hospital, clinic or home setting." Indeed, Outset Medical made clear that the Company's true value proposition would be recognized through the emerging use-at-home market rather than the more traditional acute or clinical settings it targeted historically. Outset

sought to differentiate itself in the crowded dialysis device market by highlighting its focus on the "home setting, which [the Company] estimate[d] represents a total addressable market opportunity of approximately $8.9 billion." Outset Medical contended it was "well-positioned" to "help accelerate th[e] shift to home-based hemodialysis therapy" prompted by the COVID-19 pandemic, patient preferences, government initiatives, and reimbursement changes.

4. However, devices used by non-professionals outside of a clinical setting and that can present serious health consequences like Tablo are subject to heightened scrutiny by the FDA, including post-market surveillance studies pursuant to Section 522 of the Federal Food, Drug, and Cosmetic Act (the "FDCA"), 21 C.F.R. § 822.1(a). Thus, though cleared by the FDA for sale, Tablo for use in the home setting was subject to additional studies, the results of which could require additional applications for clearance and approvals.

5. While performing further regulatory studies during the Class Period, the Company assured investors that it was conducting the studies "in accordance with the FDA approved protocol," which required an appropriate demonstration of "real-world" human testing given that the device would be used at home by non-professionals.

6. Seizing on positive prospects for sales of Tablo, the Company completed two secondary stock offerings—one in December 2020 and one in April 2021—raising more than $570 million in proceeds for the benefit of the Company and its private equity backers.

7. Undisclosed to investors, and as Defendants have now admitted, Outset Medical "continuously" made significant changes to Tablo for use in the home setting. The nature of these undisclosed changes: (1) made it likely that the FDA would order the Company to cease all marketing and selling of Tablo for use in the home pending additional applications and approvals; and (2) prevented the Company from performing the requisite "real-world" human testing on a device cleared for sale, contrary to representations to investors.

8. Investors began to learn the truth after the markets closed on May 4, 2022, when the Company announced disappointing results for the first quarter of 2022, which analysts attributed, *inter alia*, to the untested nature of Tablo in the home setting. In response to this

disclosure, and as the market digested this news, the price of Outset Medical common stock declined more than 40% over the three trading days that followed, from a closing price of $39.94 per share on Wednesday, May 4, 2022, to a closing price of $23.06 per share on Monday, May 9, 2022.

9. Outset Medical then shocked investors after the markets closed on June 13, 2022, announcing that the FDA had forced the Company to hold all shipments of Tablo for use in the home until Tablo received proper regulatory clearance. In an astonishing admission made during an "FDA Review Call" held that day with analysts, Company Chief Executive Officer ("CEO") Leslie Trigg ("Trigg") acknowledged the "ship hold" had already been in place for weeks before investors were provided this material information. Importantly, CEO Trigg disclosed for the first time that, rather than conducting studies using "real-world data" gathered in the "home environment" as the Company previously stated was required by the FDA, in reality, Outset Medical had "run with a protocol that involves a simulated use environment at a human factors lab."

10. During the same call, and as a result of the shipment hold, Outset Medical Chief Financial Officer ("CFO") Nabeel Ahmed announced the Company was "suspending our prior full-year and long-term guidance."

11. On this news, the price of Outset Medical stock fell an additional 34%, from a closing price of $20.41 per share on June 13, 2022, to a closing price of $13.46 per share on June 14, 2022.

12. Following the FDA Review Call, analysts openly questioned management's credibility, reporting a difficulty "reconcil[ing] company commentary on the shipment hold."

13. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's common stock when the truth was disclosed, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

14. 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).

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

16. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), Section 27 of the Exchange Act (15 U.S.C. § 78aa). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts and omissions charged herein, including the dissemination of materially false and misleading information to the investing public, and the omission of material information, occurred in substantial part in this Judicial District, as Outset Medical is headquartered in this District.

17. 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 communications, and the facilities of a national securities exchange.

DIVISIONAL ASSIGNMENT

18. Pursuant to Local Rule 3-2(c) and (e), this action should be assigned to the San Jose Division of this Court, as the Company is headquartered in Santa Clara County, California.

PARTIES

19. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, Plaintiff purchased Outset Medical common stock 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.

20. Defendant Outset Medical is incorporated under the laws of Delaware and has its principal executive offices in San Jose, California. Outset Medical's common stock trades on the Nasdaq Stock Market (the "NASDAQ") under the ticker symbol "OM."

21. Defendant Leslie Trigg ("Trigg") has served as Outset Medical's CEO at all relevant times and was elected as Chair of Outset Medical's Board of Directors in 2022.

22. Defendant Nabeel Ahmed ("Ahmed") has served as Outset Medical's CFO since August 2021. Ahmed joined Outset Medical in May 2020 and served as a Vice President and Controller. On July 1, 2021, the Company filed a Current Report on Form 8-K reporting Ahmed had been appointed as the Company's Interim CFO. In a subsequent Current Report on Form 8-K filed with the SEC on August 5, 2021, the Company announced Ahmed had transitioned to the permanent role of CFO, Principal Financial Officer, and Principal Accounting Officer, effective July 30, 2021.

23. Defendant Rebecca Chambers ("Chambers") was Outset Medical's CFO at all relevant times until July 16, 2021. In a Current Report on Form 8-K filed with the SEC on July 1, 2021, the Company announced Chambers notified the Company on June 28, 2021, of her decision to resign from Outset Medical effective July 16, 2021.

24. Defendants Trigg, Ahmed, and Chambers (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases, presentations to securities analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's 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 and access to material non-public information available to them, 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 that were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

25. The Company and the Individual Defendants are collectively referred to as the "Defendants."

SUBSTANTIVE ALLEGATIONS

Background

26. Outset Medical was founded in 2003 and is headquartered in San Jose, California. In March 2020, the Company's sole product, Tablo, received premarket notification and clearance under Section 510(k) of the FDCA, 21 C.F.R. § 807.81(a).

27. The 510(k) program is a marketing clearance process, pursuant to which Outset Medical had permission to market Tablo and demonstrate that it was as safe and effective as another FDA-approved device. Notably, significant modifications affecting the safety and/or efficacy of a device that has previously received 510(k) clearance may necessitate additional 510(k) applications and clearances.

28. The Company was taken public through an initial public offering ("IPO") on September 15, 2020, selling 10.29 million shares of common stock to the public at a price of $27 per share. The Company's IPO prospectus, dated September 14, 2020, instructed investors the Company had "regulatory clearances required to market the Tablo Hemodialysis System in the U.S. for use in patients . . . in an acute or chronic care facility." Moreover, Outset Medical touted that Tablo was "indicated for use in the home."

29. Throughout the Class Period, Outset Medical instructed investors that although the Company had received 510(k) clearance to sell Tablo for home use, the FDA was continuing to scrutinize the safety and efficacy of Tablo's use in the home setting. For example, in its IPO Prospectus, Outset Medical instructed investors that the FDA had "recently notified [the Company] that the Tablo System is subject to a mandatory post-market surveillance order under Section 522" of the FDCA because Tablo was a device "[the] failure [of which] would be reasonably likely to

have serious adverse health consequences, and that it is intended to be a life-sustaining or life-supporting device used outside a device user facility."

30. The Company further instructed investors that, in response to the 522 Order, it had submitted a "simulated human factors test protocol to the agency" and that it "previously committed to the FDA to conduct this study as a validation activity while the Tablo 510(k) was under review by the FDA."

31. According to the Company, the FDA essentially rejected the Company's "simulated human factors test protocol." Indeed, as Outset Medical disclosed in its 2020 Annual Report on Form 10-K, as filed with the SEC on March 22, 2021, in "late 2020" the FDA "requested additional information and notified us that we will need to conduct a new human factors study encompassing both summative and real-world data to meet the requirements of the 522 Order."

32. In the same Form 10-K, the Company advised investors it had responded to the FDA's request for additional information in January 2021, and, in March 2021, the FDA "approved our 522 study protocol." Notably, the Company assured the market it would "conduct the study in accordance with the FDA approved protocol."

Defendants' Materially False and Misleading Statements
Issued During the Class Period

33. The Class Period begins on September 15, 2020, when Outset Medical completed its IPO. The offering documents supporting the IPO informed investors the FDA had "required that we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users." Further, the Company stated that it continued "to seek opportunities for product improvements and feature enhancements, which will, from time to time, require FDA clearance or approval before commercial launch."

34. On November 11, 2020, the Company released its financial results for the third quarter of 2020. During the accompanying call with analysts that day, CEO Trigg stated the Company had "carefully and deliberately begun building the foundation for our technology [and that] [w]e're really excited about the promise of Tablo in transforming the [home hemodialysis]

market." CEO Trigg summarized the progress the Company had made in 2020 by, among other things, "secur[ing] FDA clearance for [home hemodialysis]."

35. In a conference call with analysts accompanying the Company's earnings for the fourth quarter of 2020 ended December 31, 2020, CEO Trigg declared "we remain intentionally deliberate in our strategy to expand our home market presence." Trigg continued, stating the Company remained "committed to doing it well[,] not quickly. Because our go[-]slow to go[-]fast strategy, we expect home revenue to remain modest relative to total revenue in 2021."

36. The Company filed its first Annual Report on Form 10-K with the SEC on March 22, 2021. Therein, the Company disclosed that the FDA:

> has required we conduct a human factors study, as well as conduct a detailed analysis of adverse events and complaints from home users. In response to the 522 order, we submitted a simulated human factors test protocol to the agency which leveraged testing from our validation study that was initialed in 2019. In late 2020, the FDA requested additional information and notified us that we will need to conduct a new human factors study encompassing both summative and real-world data to meet the requirements of the 522 Order. We responded to the FDA's request for additional information in January 2021 and in March 2021, the FDA approved our 522 study protocol. ***We will conduct the study in accordance with the FDA approved protocol***.

37. In a Form S-1 Registration Statement filed on April 6, 2021, in connection with the April 2021 secondary offering of stock, the Company repeated this disclosure, and again assured investors the Company would "conduct the study in accordance with the FDA approved protocol."

38. Defendants continued to give the market the impression testing data from users at home was positive. For example, on May 5, 2021, Outset Medical issued a press release announcing its financial results for the first quarter of 2021. During the accompanying call with analysts that day, CEO Trigg proclaimed that "Tablo's value proposition at home will become increasingly tangible. To date, patient data from those at home remains exceptional."

39. The Company did not provide investors with another update on the status of the FDA-required human factors study again until the Company filed its 2021 Annual Report on Form

10-K with the SEC on February 23, 2022 (the "2021 Form 10-K"). After the Company again discussed the FDA's requirement for a human factors study, the Company reported for the first time that "[w]e have made certain changes over time, including software updates, to the Tablo System, including to accommodate patient use in the home. Although we originally documented these changes in memoranda to file, we have submitted a 'catch-up' 510(k) application to the FDA which covers these design changes."

40. The Company's 2021 Form 10-K further explained that the Tablo System that included these design changes "also is the version of the Tablo System and software that we plan to use in the human factors study, we intend to initiate the human factors study upon FDA clearance. Once we are able to commence, conduct and complete our study, a final report will be provided to the FDA."

41. The above statements identified in ¶¶ 33 - 40 were materially false and/or misleading and failed to disclose material adverse factors about the Company's business, operations, and prospects, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants misled investors and/or failed to disclose that: (1) Defendants had "continuously made improvements and updates to Tablo over time since its original clearance" that required an additional 510(k) application; (2) as a result, the Company could not conduct a human factors study on a cleared device in accordance with FDA protocols; (3) the Company's inability to conduct the human factors study subjected the Company to the likelihood of the FDA imposing a "shipment hold" and marketing suspension, leaving the Company unable to sell Tablo for home use; and (4) as a result, Defendants' positive statements about the Company's business, operations, and prospects were materially false and misleading and /or lacked a reasonable basis at all relevant times.

The Truth Is Revealed

42. On May 4, 2022, after the markets closed, the Company released its results for the first quarter of 2022 ended on March 31, 2022, announcing a net loss of $36.9 million in the first quarter alone—an increase over its loss for the same quarter in 2021.

43. Nevertheless, the Company noted that it "[s]hipped record number of Tablo consoles for Home patients, reflecting continued momentum in health care providers establishing Home programs." Indeed, during the accompanying conference call with analysts, CFO Ahmed provided increased guidance for full year 2022. Pointing to "our strong performance in the first quarter," the Company's "forward visibility, and "increased conviction in our ability to execute as we plan to in 2022," Ahmed reported increased revenue guidance—from $142 million to $144 million—for the lower end of the Company's full-year 2022 guidance. Ahmed further touted how the Company's "performance in the home means that we continue to be on track to deliver home revenues of roughly mid-teens as a percent of full year 2022 revenues."

44. Analysts following the Company noted Tablo's at-home market was a factor in Outset Medical's reported loss. For example, in a research report published on May 5, 2022, Oppenheimer & Co. Inc. analyst Suraj Kalia ("Kalia") rated the Company neutral partially based on "Tablo's reliability in [the] home setting [being] unproven."

45. As the market digested the Company's reported loss and analysts' commentary, the price of Outset Medical stock declined more than 40% over the following three trading days, from a closing price of $39.94 per share on May 4, 2022, to a closing price of $23.06 per share on May 9, 2022.

46. Then, after the markets closed on June 13, 2022, the Company issued a current Report on Form 8-K that attached a press release announcing the Company "has implemented a shipment hold on the distribution of its Tablo Hemodialysis System for home use pending the Food and Drug Administration (FDA) review of and clearance of a 510(k) the company submitted for changes made since the device's original March 2020 clearance."

47. The same day, the Company held an emergency "FDA Review Call" with analysts. During the call, CEO Trigg stunned investors by reporting the Company had implemented the ship hold "in late May" which meant the Company would "not be marketing [Tablo] for home use during the shipment hold period." Unsurprisingly, Defendants acknowledged the hold would "materially impact[] our ability to meet our Q2 forecast." CEO Trigg then revealed to investors

that the Company had "continuously made improvements and updates to Tablo over time since its original clearances for acute, chronic at home." Then, and in stark contrast to the Company's prior assurances to investors that it had been conducting the 522 Study in accordance with FDA protocols requiring presentation of "real-world data" gathered in "the home environment," CEO Trigg admitted that, in reality, the Company's human factors study had been "run with a protocol that involves a simulated use environment at a human factors lab."

48. As a result of the shipment hold imposed by the FDA, CFO Ahmed told analysts during the FDA Review Call that it was "too early to provide guidance for the full year absent clarity on the timing of the review completion," and as a result, the Company was "suspending our prior full year and longer-term guidance."

49. Following the call, analysts were quick to react to these developments. Analysts with Stifel Financial and Cowen Inc. both slashed their price targets for Outset Medical by roughly 40%. Stifel analysts Rick Wise, Anton Heldman, and John McAulay directly tied the Company's disclosures to the stock price decline, reporting "we expect OM shares will weaken further today reflecting these FDA uncertainties and now-lowered near-term outlook." Oppenheimer analyst Kalia was even more direct, questioning Defendants' credibility and reporting "[w]e cannot reconcile company commentary with our understanding of [human factors] testing … and bullish commentary on 1Q call in early May." Kalia further noted that "[t]he necessity of a shipment hold for [what had been painted by the Company as] relatively marginal design changes doesn't comport, in our view."

50. In response to this news, on the following trading day, the price of Outset Medical collapsed, falling an additional 34% from a closing price of $20.41 per share on June 13, 2022, to a closing price of $13.46 per share on June 14, 2022.

CLASS ACTION ALLEGATIONS

51. Plaintiff brings this action as a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of a class, consisting of all persons and entities that purchased Outset Medical common stock between September 15, 2020, and June 13, 2022,

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.

52. The members of the Class are so numerous that joinder of all members is impracticable. 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. Throughout the Class Period, Outset Medical common stock actively traded on NASDAQ (an open and efficient market) under the symbol "OM." Millions of Outset Medical shares were traded publicly during the Class Period on the NASDAQ. As of April 22, 2022, the Company had more than 47 million shares outstanding. Record owners and other members of the Class may be identified from records maintained by Outset Medical or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

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

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

55. 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 Defendants violated the Exchange Act by the acts and omissions as alleged herein;

b. whether Defendants knew or recklessly disregarded that their statements and/or omissions were false and misleading;

c. whether documents, press releases, and other statements disseminated to the investing public and the Company's shareholders during the Class Period misrepresented material facts about the business, operations, and prospects of Outset Medical;

d. whether statements made by Defendants to the investing public during the Class Period misrepresented and/or omitted to disclose material facts about the business, operations, and prospects of Outset Medical;

e. whether the market price of Outset Medical common stock during the Class Period was artificially inflated due to the material misrepresentations and failures to correct the material misrepresentations complained of herein; and

f. the extent to which the members of the Class have sustained damages and the proper measure of damages.

56. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this suit as a class action.

UNDISCLOSED ADVERSE INFORMATION

57. The market for Outset Medical's common stock was an open, well-developed, and efficient market at all relevant times. As a result of the materially false and/or misleading statements and/or omissions particularized in this Complaint, Outset Medical's common stock traded at artificially inflated prices during the Class Period. Plaintiff and the other members of the Class purchased Outset Medical's common stock relying upon the integrity of the market price of the Company's common stock and market information relating to Outset Medical and have been damaged thereby.

58. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Outset Medical's common stock, 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 Outset Medical's business, operations, and prospects as alleged herein. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its business, thus causing the Company's common stock to be overvalued and artificially inflated or maintained at all relevant times. Defendants' materially false and/or misleading statements during the Class Period directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class who purchase the Company's common stock at artificially inflated prices and were harmed when the truth was revealed.

SCIENTER ALLEGATIONS

59. As alleged herein, Defendants acted with scienter in that Defendants knew or were reckless as to whether the public documents and statements issued or disseminated in the name of the Company during the Class Period were materially false and misleading; knew or were reckless as to whether 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.

60. As set forth herein, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Outset Medical, their control over, receipt, and/or modification of Outset Medical's allegedly materially misleading statements and omissions, and/or their positions with the Company which made them privy to confidential information concerning Outset Medical, participated in the fraudulent scheme alleged herein.

INAPPLICABILITY OF STATUTORY SAFE HARBOR

61. The federal 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.

62. 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 Outset Medical who knew that the statement was false when made.

LOSS CAUSATION

63. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss, *i.e.*, damages, suffered by Plaintiff and the Class.

64. During the Class Period, as detailed herein, Defendants made materially false and misleading statements and omissions and engaged in a scheme to deceive the market. This artificially inflated the prices of Outset Medical's common stock and operated as a fraud or deceit on the Class. When Defendants' prior misrepresentations, information alleged to have been concealed, fraudulent conduct, and/or the effect thereof were disclosed to the market, the price of Outset Medical's stock fell precipitously, as the prior artificial inflation came out of the price.

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

65. The market for Outset Medical stock 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 particularized in this Complaint, Outset Medical common stock traded at artificially inflated and/or maintained prices during the Class Period. Plaintiff and other members of the Class purchased the Company's common stock relying upon the integrity of the market price of Outset

Medical common stock and market information relating to Outset Medical and have been damaged thereby.

66. At all times relevant, the market for Outset Medical common stock was an efficient market for the following reasons, among others:

a. Outset Medical was listed and actively traded on NASDAQ, a highly efficient and automated market;

b. As a regulated issuer, Outset Medical filed periodic public reports with the SEC and/or the NASDAQ;

c. Outset Medical 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. Outset Medical 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.

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

68. 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 Class's claims are, in large part, grounded in Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business, operations, and prospects—information that

Defendants were obligated to disclose during the Class Period but did not—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 the making of investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

COUNTS AGAINST DEFENDANTS

COUNT I

For Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

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

70. During the Class Period, Defendants carried out a plan, scheme, and course of conduct that was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and maintain the market price of Outset Medical common stock; and (iii) cause Plaintiff and other members of the Class to purchase Outset Medical stock at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, and each of them, took the actions set forth herein.

71. 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 conduct that operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Outset Medical common stock in violation of Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

72. Defendants, individually and in concert, directly and indirectly, by the use, means, or instrumentalities of interstate commerce and/or the mails, engaged and participated in a

continuous course of conduct to conceal adverse material information about Outset Medical's business, operations, and prospects, as specified herein. Defendants employed devices, schemes, and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Outset Medical's business, operations, and prospects, 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 Outset Medical 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 conduct of business that operated as a fraud and deceit upon the purchasers of the Company's common stock during the Class Period.

73. Each of the Individual Defendants' primary liability and controlling person liability, arises from the following facts: (i) each of the Individual Defendants was a high-level executive and/or director at the Company during the Class Period and a member of the Company's management team or had control thereof; (ii) each of the Individual Defendants, by virtue of his 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 business, operations, and prospects; (iii) each of the Individual 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 financial condition and performance at all relevant times; and (iv) each of the Individual 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.

74. 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 Outset Medical's operating condition, business practices, and prospects from the investing public and supporting the artificially inflated and/or maintained price of its common stock. As demonstrated by Defendants' overstatements and misstatements of the Company's business, operations, 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.

75. 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 Outset Medical common stock was 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 stock trades, and/or in the absence of material adverse information that was known 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 purchased Outset Medical common stock during the Class Period at artificially inflated prices and were damaged thereby.

76. At the time of said misrepresentations and 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 of the truth regarding the problems that Outset Medical was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased their Outset Medical common stock, or, if they had purchased such common stock during the Class Period, they would not have done so at the artificially inflated prices that they paid.

77. By virtue of the foregoing, Outset Medical and the Individual Defendants each violated § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

78. 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 common stock during the Class Period.

COUNT II

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

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

80. The Individual Defendants acted as controlling persons of Outset Medical within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions with the Company, participation in, and/or awareness of the Company's operations, and intimate knowledge of the false statements filed by the Company with the SEC and disseminated to the investing public, the 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 that Plaintiff contends are false and misleading. Each of the Individual Defendants was 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. Further, the Individual Defendants signed some or all of the following reports with the SEC: the Company's 2020 and 2021 Annual Reports on Form 10-K and the Third Quarterly Report for 2020, the First, Second, and Third Quarterly Reports for 2021, and First Quarterly Report for 2022 on Form 10-Q.

81. In particular, the 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.

82. As set forth above, Outset Medical and the Individual Defendants each violated § 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, the Individual Defendants are liable pursuant to § 20(a) of the Exchange Act. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff

and other members of the Class suffered damages in connection with their purchases of the Company's common stock during the Class Period.

PRAYER FOR RELIEF

83. WHEREFORE, Plaintiff, individually and on behalf of the Class, prays for relief and judgment as follows:

a) Declaring this action to be a class action pursuant to Rule 23(a) and (b)(3) of the Federal Rules of Civil Procedure on behalf of the Class defined herein;

b) Awarding Plaintiff and the other members of the Class damages in an amount that may be proven at trial, together with interest thereon;

c) Awarding Plaintiff and the members of the Class pre-judgment and post-judgment interest, as well as their reasonable attorneys' and experts' witness fees and other costs; and

d) Awarding such other relief as this Court deems appropriate.

JURY DEMAND

Plaintiff demands a trial by jury.