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**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA**

_____, 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

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

12 **NATURE OF THE ACTION**

13 1. This is a federal securities class action on behalf of all persons or entities who
14 purchased Outset Medical common stock between September 15, 2020, and June 13, 2022,
15 inclusive (the “Class Period”) against Outset Medical and certain of its officers (collectively
16 “Defendants”) seeking to pursue remedies under the Securities Exchange Act of 1934, 15 U.S.C.
17 § 78a *et seq.* (the “Exchange Act”).

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

23 3. Throughout the Class Period, Outset Medical touted that Tablo can “serve as a
24 dialysis clinic on wheels” that had been “cleared by the [U.S.] Food and Drug Administration [(the
25 “FDA”)] for use in the hospital, clinic or home setting.” Indeed, Outset Medical made clear that
26 the Company’s true value proposition would be recognized through the emerging use-at-home
27 market rather than the more traditional acute or clinical settings it targeted historically. Outset
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1 sought to differentiate itself in the crowded dialysis device market by highlighting its focus on the
2 “home setting, which [the Company] estimate[d] represents a total addressable market opportunity
3 of approximately \$8.9 billion.” Outset Medical contended it was “well-positioned” to “help
4 accelerate th[e] shift to home-based hemodialysis therapy” prompted by the COVID-19 pandemic,
5 patient preferences, government initiatives, and reimbursement changes.

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

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

16 6. Seizing on positive prospects for sales of Tablo, the Company completed two
17 secondary stock offerings—one in December 2020 and one in April 2021—raising more than
18 \$570 million in proceeds for the benefit of the Company and its private equity backers.

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

25 8. Investors began to learn the truth after the markets closed on May 4, 2022, when
26 the Company announced disappointing results for the first quarter of 2022, which analysts
27 attributed, *inter alia*, to the untested nature of Tablo in the home setting. In response to this
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1 disclosure, and as the market digested this news, the price of Outset Medical common stock
2 declined more than 40% over the three trading days that followed, from a closing price of \$39.94
3 per share on Wednesday, May 4, 2022, to a closing price of \$23.06 per share on Monday, May 9,
4 2022.

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

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

18 11. On this news, the price of Outset Medical stock fell an additional 34%, from a
19 closing price of \$20.41 per share on June 13, 2022, to a closing price of \$13.46 per share on June
20 14, 2022.

21 12. Following the FDA Review Call, analysts openly questioned management’s
22 credibility, reporting a difficulty “reconcil[ing] company commentary on the shipment hold.”

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

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

4 21. Defendant Leslie Trigg (“Trigg”) has served as Outset Medical’s CEO at all
5 relevant times and was elected as Chair of Outset Medical’s Board of Directors in 2022.

6 22. Defendant Nabeel Ahmed (“Ahmed”) has served as Outset Medical’s CFO since
7 August 2021. Ahmed joined Outset Medical in May 2020 and served as a Vice President and
8 Controller. On July 1, 2021, the Company filed a Current Report on Form 8-K reporting Ahmed
9 had been appointed as the Company’s Interim CFO. In a subsequent Current Report on Form
10 8-K filed with the SEC on August 5, 2021, the Company announced Ahmed had transitioned to
11 the permanent role of CFO, Principal Financial Officer, and Principal Accounting Officer,
12 effective July 30, 2021.

13 23. Defendant Rebecca Chambers (“Chambers”) was Outset Medical’s CFO at all
14 relevant times until July 16, 2021. In a Current Report on Form 8-K filed with the SEC on July 1,
15 2021, the Company announced Chambers notified the Company on June 28, 2021, of her decision
16 to resign from Outset Medical effective July 16, 2021.

17 24. Defendants Trigg, Ahmed, and Chambers (collectively the “Individual
18 Defendants”), because of their positions with the Company, possessed the power and authority to
19 control the contents of the Company’s reports to the SEC, press releases, presentations to securities
20 analysts, money and portfolio managers, and institutional investors, *i.e.*, the market. The
21 Individual Defendants were provided with copies of the Company’s reports and press releases
22 alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and
23 opportunity to prevent their issuance or cause them to be corrected. Because of their positions and
24 access to material non-public information available to them, the Individual Defendants knew that
25 the adverse facts specified herein had not been disclosed to, and were being concealed from, the
26 public and that the positive representations that were being made were then materially false and/or
27 misleading. The Individual Defendants are liable for the false statements pleaded herein.

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

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

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

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

16 **Defendants’ Materially False and Misleading Statements**
17 **Issued During the Class Period**

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

24 34. On November 11, 2020, the Company released its financial results for the third
25 quarter of 2020. During the accompanying call with analysts that day, CEO Trigg stated the
26 Company had “carefully and deliberately begun building the foundation for our technology [and
27 that] [w]e’re really excited about the promise of Tablo in transforming the [home hemodialysis]
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1 market.” CEO Trigg summarized the progress the Company had made in 2020 by, among other
2 things, “secur[ing] FDA clearance for [home hemodialysis].”

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

8 36. The Company filed its first Annual Report on Form 10-K with the SEC on March
9 22, 2021. Therein, the Company disclosed that the FDA:

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

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

25 38. Defendants continued to give the market the impression testing data from users at
26 home was positive. For example, on May 5, 2021, Outset Medical issued a press release
27 announcing its financial results for the first quarter of 2021. During the accompanying call with
28 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

1 10-K with the SEC on February 23, 2022 (the “2021 Form 10-K”). After the Company again
2 discussed the FDA’s requirement for a human factors study, the Company reported for the first
3 time that “[w]e have made certain changes over time, including software updates, to the Tablo
4 System, including to accommodate patient use in the home. Although we originally documented
5 these changes in memoranda to file, we have submitted a ‘catch-up’ 510(k) application to the FDA
6 which covers these design changes.”

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

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

24 **The Truth Is Revealed**

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

1 43. Nevertheless, the Company noted that it “[s]hipped record number of Tablo
2 consoles for Home patients, reflecting continued momentum in health care providers establishing
3 Home programs.” Indeed, during the accompanying conference call with analysts, CFO Ahmed
4 provided increased guidance for full year 2022. Pointing to “our strong performance in the first
5 quarter,” the Company’s “forward visibility, and “increased conviction in our ability to execute as
6 we plan to in 2022,” Ahmed reported increased revenue guidance—from \$142 million to
7 \$144 million—for the lower end of the Company’s full-year 2022 guidance. Ahmed further touted
8 how the Company’s “performance in the home means that we continue to be on track to deliver
9 home revenues of roughly mid-teens as a percent of full year 2022 revenues.”

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

14 45. As the market digested the Company’s reported loss and analysts’ commentary, the
15 price of Outset Medical stock declined more than 40% over the following three trading days, from
16 a closing price of \$39.94 per share on May 4, 2022, to a closing price of \$23.06 per share on May
17 9, 2022.

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

23 47. The same day, the Company held an emergency “FDA Review Call” with analysts.
24 During the call, CEO Trigg stunned investors by reporting the Company had implemented the ship
25 hold “in late May” which meant the Company would “not be marketing [Tablo] for home use
26 during the shipment hold period.” Unsurprisingly, Defendants acknowledged the hold would
27 “materially impact[] our ability to meet our Q2 forecast.” CEO Trigg then revealed to investors
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1 that the Company had “continuously made improvements and updates to Tablo over time since its
2 original clearances for acute, chronic at home.” Then, and in stark contrast to the Company’s prior
3 assurances to investors that it had been conducting the 522 Study in accordance with FDA
4 protocols requiring presentation of “real-world data” gathered in “the home environment,” CEO
5 Trigg admitted that, in reality, the Company’s human factors study had been “run with a protocol
6 that involves a simulated use environment at a human factors lab.”

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

11 49. Following the call, analysts were quick to react to these developments. Analysts
12 with Stifel Financial and Cowen Inc. both slashed their price targets for Outset Medical by roughly
13 40%. Stifel analysts Rick Wise, Anton Heldman, and John McAulay directly tied the Company’s
14 disclosures to the stock price decline, reporting “we expect OM shares will weaken further today
15 reflecting these FDA uncertainties and now-lowered near-term outlook.” Oppenheimer analyst
16 Kalia was even more direct, questioning Defendants’ credibility and reporting “[w]e cannot
17 reconcile company commentary with our understanding of [human factors] testing ... and bullish
18 commentary on 1Q call in early May.” Kalia further noted that “[t]he necessity of a shipment hold
19 for [what had been painted by the Company as] relatively marginal design changes doesn’t
20 comport, in our view.”

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

24 **CLASS ACTION ALLEGATIONS**

25 51. Plaintiff brings this action as a class action pursuant to Rule 23(a) and (b)(3) of the
26 Federal Rules of Civil Procedure on behalf of a class, consisting of all persons and entities that
27 purchased Outset Medical common stock between September 15, 2020, and June 13, 2022,
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1 inclusive, and who were damaged thereby (the “Class”). Excluded from the Class are Defendants,
2 the officers and directors of the Company, at all relevant times, members of their immediate
3 families and their legal representatives, heirs, successors, or assigns, and any entity in which
4 Defendants have or had a controlling interest.

5 52. The members of the Class are so numerous that joinder of all members is
6 impracticable. While the exact number of Class members is unknown to Plaintiff at this time and
7 can only be ascertained through appropriate discovery, Plaintiff believes that there are at least
8 hundreds or thousands of members in the proposed Class. Throughout the Class Period, Outset
9 Medical common stock actively traded on NASDAQ (an open and efficient market) under the
10 symbol “OM.” Millions of Outset Medical shares were traded publicly during the Class Period on
11 the NASDAQ. As of April 22, 2022, the Company had more than 47 million shares
12 outstanding. Record owners and other members of the Class may be identified from records
13 maintained by Outset Medical or its transfer agent and may be notified of the pendency of this
14 action by mail, using a form of notice similar to that customarily used in securities class actions.

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

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

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

- 24 a. whether Defendants violated the Exchange Act by the acts and omissions
25 as alleged herein;
- 26 b. whether Defendants knew or recklessly disregarded that their statements
27 and/or omissions were false and misleading;

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

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

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

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

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

18 **UNDISCLOSED ADVERSE INFORMATION**

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

26 58. During the Class Period, Defendants materially misled the investing public,
27 thereby inflating the price of Outset Medical's common stock, by publicly issuing false and/or
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1 misleading statements and/or omitting to disclose material facts necessary to make Defendants'
2 statements, as set forth herein, not false and/or misleading. The statements and omissions were
3 materially false and/or misleading because they failed to disclose material adverse information
4 and/or misrepresented the truth about Outset Medical's business, operations, and prospects as
5 alleged herein. These material misstatements and/or omissions had the cause and effect of creating
6 in the market an unrealistically positive assessment of the Company and its business, thus causing
7 the Company's common stock to be overvalued and artificially inflated or maintained at all
8 relevant times. Defendants' materially false and/or misleading statements during the Class Period
9 directly or proximately caused or were a substantial contributing cause of the damages sustained
10 by Plaintiff and other members of the Class who purchase the Company's common stock at
11 artificially inflated prices and were harmed when the truth was revealed.

12 **SCIENTER ALLEGATIONS**

13 59. As alleged herein, Defendants acted with scienter in that Defendants knew or were
14 reckless as to whether the public documents and statements issued or disseminated in the name of
15 the Company during the Class Period were materially false and misleading; knew or were reckless
16 as to whether such statements or documents would be issued or disseminated to the investing
17 public, and knowingly and substantially participated or acquiesced in the issuance or dissemination
18 of such statements or documents as primary violations of the federal securities laws.

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

24 **INAPPLICABILITY OF STATUTORY SAFE HARBOR**

25 61. The federal statutory safe harbor provided for forward-looking statements under
26 certain circumstances does not apply to any of the allegedly false statements pleaded in this
27 Complaint. The statements alleged to be false and misleading herein all relate to then-existing
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1 facts and conditions. In addition, to the extent certain of the statements alleged to be false may be
2 characterized as forward-looking, they were not identified as “forward-looking statements” when
3 made, and there were no meaningful cautionary statements identifying important factors that could
4 cause actual results to differ materially from those in the purportedly forward-looking statements.

5 62. In the alternative, to the extent that the statutory safe harbor is determined to apply
6 to any forward-looking statements pleaded herein, Defendants are liable for those false forward-
7 looking statements because at the time each of those forward-looking statements was made, the
8 speaker had actual knowledge that the forward-looking statement was materially false or
9 misleading, and/or the forward-looking statement was authorized or approved by an executive
10 officer of Outset Medical who knew that the statement was false when made.

11 **LOSS CAUSATION**

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

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

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

22 65. The market for Outset Medical stock was open, well-developed, and efficient at all
23 relevant times. As a result of the materially false and/or misleading statements and/or failures to
24 disclose particularized in this Complaint, Outset Medical common stock traded at artificially
25 inflated and/or maintained prices during the Class Period. Plaintiff and other members of the Class
26 purchased the Company’s common stock relying upon the integrity of the market price of Outset
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1 Medical common stock and market information relating to Outset Medical and have been damaged
2 thereby.

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

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

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

9 c. Outset Medical regularly communicated with public investors via
10 established market communication mechanisms, including through regular dissemination of press
11 releases on the national circuits of major newswire services and through other wide-ranging public
12 disclosures, such as communications with the financial press and other similar reporting services;
13 and/or

14 d. Outset Medical was followed by securities analysts employed by brokerage
15 firms who wrote reports about the Company, and these reports were distributed to the sales force
16 and certain customers of their respective brokerage firms. Each of these reports was publicly
17 available and entered the public marketplace.

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

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

6 **COUNTS AGAINST DEFENDANTS**

7 **COUNT I**

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

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

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

18 71. Defendants: (i) employed devices, schemes, and artifices to defraud; (ii) made
19 untrue statements of material fact and/or omitted to state material facts necessary to make the
20 statements not misleading; and (iii) engaged in acts, practices, and a course of conduct that
21 operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to
22 maintain artificially high market prices for Outset Medical common stock in violation of Section
23 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either
24 as primary participants in the wrongful and illegal conduct charged herein or as controlling persons
25 as alleged below.

26 72. Defendants, individually and in concert, directly and indirectly, by the use, means,
27 or instrumentalities of interstate commerce and/or the mails, engaged and participated in a
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1 continuous course of conduct to conceal adverse material information about Outset Medical's
2 business, operations, and prospects, as specified herein. Defendants employed devices, schemes,
3 and artifices to defraud, while in possession of material adverse non-public information and
4 engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors
5 of Outset Medical's business, operations, and prospects, which included the making of, or the
6 participation in the making of, untrue statements of material facts and/or omitting to state material
7 facts necessary in order to make the statements made about Outset Medical and its business,
8 operations, and future prospects in light of the circumstances under which they were made, not
9 misleading, as set forth more particularly herein, and engaged in transactions, practices, and a
10 course of conduct of business that operated as a fraud and deceit upon the purchasers of the
11 Company's common stock during the Class Period.

12 73. Each of the Individual Defendants' primary liability and controlling person
13 liability, arises from the following facts: (i) each of the Individual Defendants was a high-level
14 executive and/or director at the Company during the Class Period and a member of the Company's
15 management team or had control thereof; (ii) each of the Individual Defendants, by virtue of his
16 responsibilities and activities as a senior officer and/or director of the Company, was privy to and
17 participated in the creation, development, and reporting of the Company's business, operations,
18 and prospects; (iii) each of the Individual Defendants enjoyed significant personal contact and
19 familiarity with the other Defendants and was advised of and had access to, other members of the
20 Company's management team, internal reports, and other data and information about the
21 Company's financial condition and performance at all relevant times; and (iv) each of the
22 Individual Defendants was aware of the Company's dissemination of information to the investing
23 public, which they knew and/or recklessly disregarded was materially false and misleading.

24 74. Defendants had actual knowledge of the misrepresentations and/or omissions of
25 material facts set forth herein or acted with reckless disregard for the truth in that they failed to
26 ascertain and to disclose such facts, even though such facts were available to them. Such
27 Defendants' material misrepresentations and/or omissions were done knowingly or recklessly and
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1 for the purpose and effect of concealing Outset Medical's operating condition, business practices,
2 and prospects from the investing public and supporting the artificially inflated and/or maintained
3 price of its common stock. As demonstrated by Defendants' overstatements and misstatements of
4 the Company's business, operations, and prospects throughout the Class Period, Defendants, if
5 they did not have actual knowledge of the misrepresentations and/or omissions alleged, were
6 reckless in failing to obtain such knowledge by deliberately refraining from taking those steps
7 necessary to discover whether those statements were false or misleading.

8 75. As a result of the dissemination of the materially false and/or misleading
9 information and/or failure to disclose material facts, as set forth above, the market price of Outset
10 Medical common stock was artificially inflated, and relying directly or indirectly on the false and
11 misleading statements made by Defendants or upon the integrity of the market in which the stock
12 trades, and/or in the absence of material adverse information that was known or recklessly
13 disregarded by Defendants, but not disclosed in public statements by Defendants during the Class
14 Period, Plaintiff and the other members of the Class purchased Outset Medical common stock
15 during the Class Period at artificially inflated prices and were damaged thereby.

16 76. At the time of said misrepresentations and omissions, Plaintiff and other members
17 of the Class were ignorant of their falsity and believed them to be true. Had Plaintiff and the other
18 members of the Class and the marketplace known of the truth regarding the problems that Outset
19 Medical was experiencing, which were not disclosed by Defendants, Plaintiff and other members
20 of the Class would not have purchased their Outset Medical common stock, or, if they had
21 purchased such common stock during the Class Period, they would not have done so at the
22 artificially inflated prices that they paid.

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

25 78. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the
26 other members of the Class suffered damages in connection with their purchases of the Company's
27 common stock during the Class Period.

1 **COUNT II**

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

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

6 80. The Individual Defendants acted as controlling persons of Outset Medical within
7 the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level
8 positions with the Company, participation in, and/or awareness of the Company's operations, and
9 intimate knowledge of the false statements filed by the Company with the SEC and disseminated
10 to the investing public, the Individual Defendants had the power to influence and control and did
11 influence and control, directly or indirectly, the decision-making of the Company, including the
12 content and dissemination of the various statements that Plaintiff contends are false and
13 misleading. Each of the Individual Defendants was provided with or had unlimited access to
14 copies of the Company's reports, press releases, public filings, and other statements alleged by
15 Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the
16 ability to prevent the issuance of the statements or cause the statements to be corrected. Further,
17 the Individual Defendants signed some or all of the following reports with the SEC: the Company's
18 2020 and 2021 Annual Reports on Form 10-K and the Third Quarterly Report for 2020, the First,
19 Second, and Third Quarterly Reports for 2021, and First Quarterly Report for 2022 on Form
20 10-Q.

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

25 82. As set forth above, Outset Medical and the Individual Defendants each violated
26 § 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their
27 position as controlling persons, the Individual Defendants are liable pursuant to § 20(a) of the
28 Exchange Act. As a direct and proximate result of these Defendants' wrongful conduct, Plaintiff

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

3 **PRAYER FOR RELIEF**

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

- 6 a) Declaring this action to be a class action pursuant to Rule 23(a) and (b)(3) of the
7 Federal Rules of Civil Procedure on behalf of the Class defined herein;
- 8 b) Awarding Plaintiff and the other members of the Class damages in an amount that
9 may be proven at trial, together with interest thereon;
- 10 c) Awarding Plaintiff and the members of the Class pre-judgment and post-judgment
11 interest, as well as their reasonable attorneys' and experts' witness fees and other
12 costs; and
- 13 d) Awarding such other relief as this Court deems appropriate.

14 **JURY DEMAND**

15 Plaintiff demands a trial by jury.
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