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

PLYMOUTH COUNTY RETIREMENT  
ASSOCIATION, 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, Plymouth County Retirement Association (“Plaintiff”), by and through its  
2 attorneys, alleges the following upon information and belief, except as to allegations concerning  
3 Plaintiff, which are alleged upon personal knowledge. Plaintiff’s information and belief are based  
4 upon, among other things, its counsel’s investigation, which includes, without limitation:  
5 (a) review and analysis of public filings made by Outset Medical, Inc. (“Outset Medical” or the  
6 “Company”) with the U.S. Securities and Exchange Commission (the “SEC”); (b) review and  
7 analysis of press releases and other publications disseminated by Defendants (defined below) and  
8 other 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) review  
10 of other publicly available information concerning the Company and the Individual Defendants  
11 (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.

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1 **JURISDICTION AND VENUE**

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

5 15. This Court has jurisdiction over the subject matter of this action pursuant to  
6 28 U.S.C. § 1331, Section 27 of the Exchange Act (15 U.S.C. § 78aa).

7 16. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b), Section  
8 27 of the Exchange Act (15 U.S.C. § 78aa). Substantial acts in furtherance of the alleged fraud or  
9 the effects of the fraud have occurred in this Judicial District. Many of the acts and omissions  
10 charged herein, including the dissemination of materially false and misleading information to the  
11 investing public, and the omission of material information, occurred in substantial part in this  
12 Judicial District, as Outset Medical is headquartered in this District.

13 17. In connection with the acts, transactions, and conduct alleged herein, Defendants,  
14 directly and indirectly, used the means and instrumentalities of interstate commerce, including the  
15 U.S. Mail, interstate telephone communications, and the facilities of a national securities exchange.

16 **DIVISIONAL ASSIGNMENT**

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

19 **PARTIES**

20 19. Plaintiff Plymouth County Retirement Association is a public pension system  
21 organized for the benefit of current and retired municipal and county employees of Plymouth  
22 County, Massachusetts. Plaintiff manages approximately \$1.2 billion in assets. As set forth in the  
23 accompanying certification, incorporated by reference herein, Plaintiff purchased Outset Medical  
24 common stock during the Class Period and suffered damages as a result of the federal securities  
25 law violations and false and/or misleading statements and/or material omissions alleged herein.

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