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

CHRIS PORCELLI, Individually and on  
Behalf of All Others Similarly Situated,

Plaintiff,

v.

OUTSET MEDICAL, INC., LESLIE TRIGG,  
and NABEEL AHMED,

Defendants.

Case No.

**CLASS ACTION COMPLAINT FOR  
VIOLATIONS OF THE FEDERAL  
SECURITIES LAWS**

1 Plaintiff Chris Porcelli (“Plaintiff”), individually and on behalf of all others similarly  
2 situated, by and through his attorneys, alleges the following upon information and belief, except as  
3 to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff’s  
4 information and belief is based upon, among other things, his counsel’s investigation, which  
5 includes without limitation: (a) review and analysis of regulatory filings made by Outset Medical,  
6 Inc. (“Outset Medical” or the “Company”) with the United States (“U.S.”) Securities and Exchange  
7 Commission (“SEC”); (b) review and analysis of press releases and media reports issued by and  
8 disseminated by Outset Medical; and (c) review of other publicly available information concerning  
9 Outset Medical.

10 **NATURE OF THE ACTION AND OVERVIEW**

11 1. This is a class action on behalf of persons and entities that purchased or otherwise  
12 acquired Outset Medical securities between August 1, 2022 and August 7, 2024, inclusive (the  
13 “Class Period”). Plaintiff pursues claims against the Defendants under the Securities Exchange Act  
14 of 1934 (the “Exchange Act”).

15 2. Outset Medical is a medical technology company. Its primary products are the Tablo  
16 series devices used in dialysis care, including the Tablo Hemodialysis System and the TabloCart.  
17 The Tablo Hemodialysis System is a dialysis machine. The TabloCart is an accessory to Tablo  
18 Hemodialysis System. On July 29, 2022, the Company received Section 510(k) clearance from the  
19 United States Food and Drug Administration (“FDA”) for the Tablo Hemodialysis System as  
20 “indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration,  
21 in an acute or chronic care facility” and “in the home.”

22 3. On July 7, 2023, after the market closed, Outset Medical disclosed that it had  
23 received a Warning Letter from the FDA which “asserted that certain materials . . . promote  
24 continuous renal replacement therapy (CRRT), a modality outside of the current indications for the  
25 Tablo Hemodialysis System” and “assert[ed] that the TabloCart with Prefiltration . . . requires prior  
26 510(k) clearance for marketing authorization.” and that the Company would “work collaboratively  
27 with the FDA to resolve this observation, including potentially submitting a 510(k) on TabloCart.”  
28

1           4.       On this news, Outset Medical’s stock price fell \$1.20, or 5.9%, to close at \$19.26 per  
2 share on July 10, 2023, on unusually heavy trading volume.

3           5.       On August 2, 2023, after the market closed, the Company issued a press release  
4 which announced a **“*Shipment Pause of TabloCart with Prefiltration Pending 510(k) Clearance.*”**

5           6.       On this news, Outset Medical’s stock price fell \$1.97, or 10.18%, to close at \$17.39  
6 per share on August 3, 2023, on unusually heavy trading volume.

7           7.       On October 12, 2023, after the market closed, the Company revealed that revenue  
8 growth had been significantly impacted by the FDA’s warning letter. Specifically, the Company  
9 issued a press release announcing preliminary third quarter 2023 financial results, as well as updated  
10 financial guidance for 2023 revenue, which reflected that “[g]rowth in the quarter was dampened  
11 by a larger-than-expected impact in the field from the recent FDA warning letter.”

12          8.       On this news, the Company’s share price fell \$3.38, or 49.9%, to close at \$3.39 per  
13 share on October 13, 2023, on unusually heavy trading volume.

14          9.       On August 7, 2024, after the market closed, Outset Medical released its second  
15 quarter 2024 financial results, significantly missing consensus estimates and lowering its full year  
16 2024 revenue guidance by \$39 million at the midpoint. The Company disclosed it would be forced  
17 to take “clear steps to improve our execution” including “sales team and process restructuring.” As  
18 a result, the Company disclosed it would be unable to deliver on a post-approval sales ramp of  
19 TabloCart previously forecast.

20          10.      On this news, the Company’s share price fell \$2.33, or 68.53%, to close at \$1.07 per  
21 share on August 8, 2024, on unusually heavy trading volume.

22          11.      Throughout the Class Period, Defendants made materially false and/or misleading  
23 statements, as well as failed to disclose material adverse facts about the Company’s business,  
24 operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) the Tablo  
25 products were marketed for continuous renal replacement therapy, which is not one of the  
26 indications approved by the FDA; (2) that, as a result, Outset Medical was reasonably likely to  
27 submit an additional 510(k) application for the Tablo products; (3) that there was a substantial risk  
28 that the Company would cease sales of the Tablo products pending FDA approval of additional

1 indications; (4) that Outset Medical lacked the sales team and process to execute on the ramp of  
2 Tablo sales; (5) that, as a result of the foregoing, the Company's revenue growth would be adversely  
3 impacted; and (6) that, as a result of the foregoing, Defendants' positive statements about the  
4 Company's business, operations, and prospects were materially misleading and/or lacked a  
5 reasonable basis.

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

### 9 **JURISDICTION AND VENUE**

10 13. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act  
11 (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §  
12 240.10b-5).

13 14. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C.  
14 § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

15 15. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section  
16 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud  
17 or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein,  
18 including the dissemination of materially false and/or misleading information, occurred in  
19 substantial part in this Judicial District. In addition, the Company's principal executive offices are  
20 located in this District.

21 16. In connection with the acts, transactions, and conduct alleged herein, Defendants  
22 directly and indirectly used the means and instrumentalities of interstate commerce, including the  
23 United States mail, interstate telephone communications, and the facilities of a national securities  
24 exchange.

### 25 **PARTIES**

26 17. Plaintiff Chris Porcelli, as set forth in the accompanying certification, incorporated  
27 by reference herein, purchased Outset Medical securities during the Class Period, and suffered  
28

1 damages as a result of the federal securities law violations and false and/or misleading statements  
2 and/or material omissions alleged herein.

3 18. Defendant Outset Medical is incorporated under the laws of Delaware with its  
4 principal executive offices located in San Jose, California. Outset Medical’s common stock trades  
5 on the NASDAQ exchange under the symbol “OM.”

6 19. Defendant Leslie Trigg (“Trigg”) was the Company’s Chief Executive Officer  
7 (“CEO”) at all relevant times.

8 20. Defendant Nabeel Ahmed (“Ahmed”) was the Company’s Chief Financial Officer  
9 (“CFO”) at all relevant times.

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

## 21 SUBSTANTIVE ALLEGATIONS

### 22 Background

23 22. Outset Medical is a medical technology company. Its primary products are the Tablo  
24 series devices used in dialysis care, including the Tablo Hemodialysis System and the TabloCart.  
25 The Tablo Hemodialysis System is a dialysis machine. The TabloCart is an accessory to Tablo  
26 Hemodialysis System. On July 29, 2022, the Company received Section 510(k) clearance from the  
27 FDA for the Tablo Hemodialysis System as “indicated for use in patients with acute and/or chronic  
28 renal failure, with or without ultrafiltration, in an acute or chronic care facility” and “in the home.”

1 **Materially False and Misleading**

2 **Statements Issued During the Class Period**

3 23. The Class Period begins on August 1, 2022.<sup>1</sup> On that day, the Company announced  
4 that it had resumed shipment of Tablo Systems for home use because the FDA had approved its  
5 510(k) submission. In a press release, the Company stated, in relevant part:

6 Outset Medical, Inc. (Nasdaq: OM) (“Outset” or the “Company”), a medical  
7 technology company pioneering a first-of-its-kind technology to reduce the cost and  
8 complexity of dialysis, ***today announced clearance by the Food and Drug  
Administration of its previously disclosed 510(k) submission and resumption of  
Tablo® Hemodialysis System shipments for home use.***

9 The Company also reported financial results for the second quarter ended June 30,  
10 2022 and provided financial guidance for 2022. Revenue for the second quarter  
11 totaled \$25.1 million, in line with guidance provided on June 13, 2022. Gross margin  
for the second quarter was 15.1%, compared to 4.2% in the second quarter of 2021  
and 14.5% in the first quarter of 2022.

12 “We are pleased to begin supporting new patients in the home again and helping  
13 them achieve autonomy and control over where and when they dialyze,” said Leslie  
14 Trigg, Chair and Chief Executive Officer. “As we look to the second half of the year,  
15 we see no change in underlying demand for Tablo. ***However, we have reflected in  
our guidance the staffing and inflationary pressures our provider customers are  
facing, as well as the work we need to do to regain commercial momentum  
following release of the Tablo ship hold.***”

16 24. On August 1, 2022, the Company submitted its quarterly report for the fiscal period  
17 ended June 30, 2022 on a Form 10-Q filed with the SEC, affirming the previously reported financial  
18 results. The report stated the following regarding the Company’s sales practices and FDA approval:

19 ***Tablo is cleared by the FDA for use in the hospital, clinic, or home setting.***

20 \* \* \*

21 ***In late July 2022, the FDA cleared our 510(k) application of Tablo for patient use  
22 in the home and we have resumed marketing and shipping Tablo for home use.***

23 ***Driving adoption of Tablo in the acute care setting has been our primary focus to  
24 date.*** We have invested in growing our economic and clinical evidence, built a  
25 veteran sales and clinical support team with significant expertise, and implemented  
26 a comprehensive training and customer experience program. Our experience in the  
acute care market has demonstrated Tablo’s clinical flexibility and operational  
27 versatility, while also delivering meaningful cost savings to the providers. We plan  
to continue leveraging our commercial infrastructure to broaden our installed base in

28 <sup>1</sup> Unless otherwise stated, all emphasis in bold and italics hereinafter is added.

1 the acute care market as well as driving utilization and fleet expansion with our  
2 existing customers.

3 25. On November 8, 2022, the Company issued a press release announcing the  
4 Company's financial results for the quarter ended September 30, 2022, stating in relevant part:

5 • **Recorded net revenue of \$27.8 million in the third quarter of 2022**, a 5.5%  
6 increase compared to \$26.3 million in the third quarter of 2021 and a 10.8% increase  
7 compared to \$25.1 million in the second quarter of 2022

8 • Achieved **gross margin for the third quarter of 2022 of 15.6%**, compared to 11.2%  
9 in the third quarter of 2021 and 15.1% in the second quarter of 2022

10 • **Resumed shipments to new home patients, and grew the Tablo home patient base  
11 beyond initial expectations for the third quarter**

12 • Awarded five-year contract by the Department of Veterans Affairs, enabling Tablo  
13 to be sold into the 106 VA hospitals across the U.S. as well as into home settings

14 \* \* \*

15 **Full Year 2022 Financial Guidance**

16 Outset now **projects revenue for 2022 of \$111 million to \$113 million**, which  
17 represents 8% to 10% growth over 2021. This updated guidance compares to prior  
18 2022 guidance of \$105 million to \$110 million.

19 26. On November 9, 2022, the Company submitted its quarterly report for the fiscal  
20 period ended September 30, 2022 on a Form 10-Q filed with the SEC, affirming the previously  
21 reported financial results. The report stated the following regarding the Company's sales practices  
22 and FDA approval:

23 **Tablo is cleared by the FDA for use in the hospital, clinic, or home setting.** In May  
24 2022, we implemented a shipment hold on the distribution and marketing of Tablo  
25 for use in the home environment pending the FDA's review and clearance of a 510(k)  
26 application we submitted for changes made since the device's original March 2020  
27 clearance.

28 \* \* \*

**In late July 2022, the FDA cleared our 510(k) application of Tablo for patient use  
in the home and we resumed marketing and shipping Tablo for home use.**

**Driving adoption of Tablo in the acute care setting has been our primary focus to  
date.** We have invested in growing our economic and clinical evidence, **built a  
veteran sales and clinical support team with significant expertise, and implemented  
a comprehensive training and customer experience program.**





1 **Tablo is an FDA-cleared single enterprise solution for hemodialysis, comprised of**  
2 **a compact console with integrated water purification,** on-demand dialysate  
production and advanced software and connectivity capabilities.

3 \* \* \*

4 The **Tablo system is comprised of the following components:**

5 \* \* \*

6 We recently introduced **TabloCart**, a non-medical accessory for the Tablo  
7 Hemodialysis System that provides added maneuverability and optional prefiltration  
storage.

8 \* \* \*

9 Driving adoption of Tablo in the acute care setting has been our primary focus to  
10 date. We have invested in growing our economic and clinical evidence, **built a**  
**veteran sales and clinical support team with significant expertise, and implemented**  
11 **a comprehensive training and customer experience program.**

12 \* \* \*

13 We sell our solution through our direct sales organization, which covers most major  
14 metropolitan markets in the United States. **Our sales organization is comprised of**  
**our capital sales team, responsible for generating new customer demand for Tablo,**  
**and our clinical sales team, responsible for driving utilization and fleet expansion**  
15 **of Tablo consoles at existing customer sites.**

16 \* \* \*

17 **We believe the ability to leverage one team to serve both markets will result in**  
**significant productivity and cost optimization as we continue to scale our business.**

18 30. On May 3, 2023, the Company issued a press release announcing first quarter 2023  
19 financial results for the quarter ended March 31, 2023, which reported the Company's quarterly  
20 revenue and an updated Full Year 2023 guidance, and stated in relevant part:

21 **Recent Highlights**

22 • Recorded **net revenue of \$33.5 million in the first quarter**, a 9.5% increase  
23 compared to \$30.6 million in the first quarter of 2022, and a 4.6% increase compared  
to \$32.0 million in the fourth quarter of 2022

24 • Achieved **gross margin for the first quarter of 19.2%** (20.3% on a non-GAAP  
25 basis), compared to 14.5% (14.8% on a non-GAAP basis) in the first quarter of 2022

26 \* \* \*

27 **Full Year 2023 Financial Guidance**

28 Outset now projects **revenue for 2023 to range from \$144 million to \$150 million**,  
which represents approximately 25% to 30% growth over the Company's fiscal year

1 2022 revenue. This updated guidance compares to **prior 2023 revenue guidance of**  
2 **\$140 million to \$150 million.** In addition, the Company expects **gross margin for**  
3 **the year to be in the low-20% range, up from its prior guidance** of approximately  
4 20%, and exiting the fourth quarter in the mid-20% range.

5 31. On May 4, 2023, the Company submitted its quarterly report for the period ended  
6 March 31, 2023, on a Form 10-Q filed with the SEC, affirming the previously reported financial  
7 results. The report stated the following regarding the Company's sales practices:

8 Tablo is **cleared by the FDA for use in the hospital, clinic, or home setting.**

9 \* \* \*

10 In late July 2022, **the FDA cleared our 510(k) application of Tablo** for patient use  
11 in the home and we resumed marketing and shipping Tablo for home use.

12 \* \* \*

13 We primarily sell our solutions through our direct sales organization, which covers  
14 most major metropolitan markets in the United States. **Our sales organization is**  
15 **comprised of our capital sales team, responsible for generating new customer**  
16 **demand for Tablo, and our clinical sales team, responsible for driving utilization**  
17 **and fleet expansion of Tablo consoles at existing customer sites.**

18 \* \* \*

19 We believe the ability to leverage one team to serve both markets will result in  
20 significant productivity and cost optimization as we continue to scale our business.

21 32. The above statements identified in ¶¶ 23-31 were materially false and/or misleading,  
22 and failed to disclose material adverse facts about the Company's business, operations, and  
23 prospects. Specifically, Defendants failed to disclose to investors: (1) the Tablo products were  
24 marketed for continuous renal replacement therapy, which is not one of the indications approved by  
25 the FDA; (2) that, as a result, Outset Medical was reasonably likely to submit an additional 510(k)  
26 application for the Tablo products; (3) that there was a substantial risk that the Company would  
27 cease sales of the Tablo products pending FDA approval of additional indications; (4) that Outset  
28 Medical lacked the sales team and process to execute on the ramp of Tablo sales; (5) that, as a result  
of the foregoing, the Company's revenue growth would be adversely impacted; and (6) that, as a  
result of the foregoing, Defendants' positive statements about the Company's business, operations,  
and prospects were materially misleading and/or lacked a reasonable basis.

1           33.     The truth began to emerge on July 7, 2023, after the market closed, when Outset  
2 Medical disclosed that it had been warned by the FDA of off-label marketing of the Tablo.  
3 Specifically, in a Form 8-K filed with the SEC, Outset Medical stated that it received a Warning  
4 Letter from the FDA which “asserted that certain materials . . . promote continuous renal  
5 replacement therapy (CRRT), a modality outside of the current indications for the Tablo  
6 Hemodialysis System” and “assert[ed] that the TabloCart with Prefiltration . . . requires prior 510(k)  
7 clearance for marketing authorization.” The Company stated, in relevant part:

8           As previously disclosed by the Company in its Annual Report on Form 10-K filed  
9 on February 13, 2023, the FDA issued an FDA Form-483 identifying four  
10 inspectional observations resulting from an FDA inspection that concluded on  
11 February 10, 2023. The Company provided its response plan to the FDA on March  
12 3, 2023, and has since completed the associated remediation workstreams to fully  
13 address these observations.

14           The Warning Letter raises two additional observations. The first observation asserts  
15 that certain materials reviewed by the FDA and found on the Company’s website  
16 promote continuous renal replacement therapy (CRRT), a modality outside of the  
17 current indications for the Tablo® Hemodialysis System. The Company believes this  
18 concern has been effectively addressed through labeling and promotional changes  
19 already underway.

20           The second observation asserts that the TabloCart with Prefiltration (the  
21 “TabloCart”), requires prior 510(k) clearance for marketing authorization.  
22 TabloCart, an accessory to the Tablo System, launched in the third quarter of 2022  
23 and sales to date have not been material to the Company’s financial results. The  
24 Company intends to work collaboratively with the FDA to resolve this observation,  
25 including potentially submitting a 510(k) on TabloCart.

26           The Warning Letter does not request the restriction of the manufacture, production  
27 or shipment of the Tablo System in the United States nor does it request the  
28 withdrawal of the Tablo System from the U.S. marketplace.

          The Company intends to fully cooperate with the FDA, including by responding  
within 15 business days, to expeditiously and completely resolve the Warning Letter.  
The Company cannot, however, give any assurances that the FDA will be satisfied  
with the Company’s actions taken in response to the matters raised in the Warning  
Letter. The Company also cannot give any assurances as to the timing of the  
resolution of such matters.

          34.     On this news, Outset Medical’s stock price fell \$1.20, or 5.9%, to close at \$19.26 per  
share on July 10, 2023, on unusually heavy trading volume.

          35.     The truth continued to emerge on August 2, 2023, after the market closed, when the  
Company announced a shipment pause of TabloCart pending FDA approval. Specifically, Outset  
Medical issued a press release which announced second quarter 2023 financial results, including

1 quarterly revenue of \$36.0 million and total quarterly gross profit of \$7.7 million. The press release  
2 also stated the Company “*Announces Shipment Pause of TabloCart with Prefiltration Pending*  
3 *510(k) Clearance.*” The press release further provided the Company’s full year 2023 guidance,  
4 stating in relevant part:

5 The Company also announced it has paused the shipment of TabloCart with  
6 Prefiltration, an accessory for the Tablo System, pending the Food and Drug  
Administration’s clearance of a 510(k) the company plans to submit later this month.

7 “Since receiving the Warning Letter on July 6, we have made the decision to file a  
8 510(k) for TabloCart with Prefiltration and pause distribution of the product until a  
9 510(k) clearance has been granted,” added Trigg. “As we look ahead to the second  
half of the year, we expect our strong momentum both in the acute and home end  
markets to continue to drive the business.”

10 \* \* \*

11 Outset *reiterated its 2023 revenue guidance range of \$144 million to \$150 million,*  
12 *and now expects to be at the low end of this range as a result of the shipment pause*  
13 *for TabloCart with Prefiltration.* The Company reaffirmed its gross margin  
guidance for the year to be in the low-20% range, exiting the fourth quarter in the  
mid-20% range.

14 36. On this news, Outset Medical’s stock price fell \$1.97, or 10.18%, to close at \$17.39  
15 per share on August 3, 2023, on unusually heavy trading volume.

16 37. On August 3, 2023, the Company submitted its quarterly report for the period ended  
17 June 30, 2023 on a Form 10-Q filed with the SEC, affirming the previously reported financial results.  
18 The report stated the following regarding the Company’s sales practices:

19 Although we evaluated TabloCart with Prefiltration prior to marketing and  
20 distributing the product and concluded that no marketing authorization was  
necessary, *we have paused distribution of TabloCart with Prefiltration pending the*  
21 *FDA’s review and clearance of the 510(k) application we plan to submit.*

22 \* \* \*

23 Driving adoption of Tablo in the acute care setting has been our primary focus to  
24 date. *We have invested in growing our economic and clinical evidence, built a*  
25 *veteran sales and clinical support team with significant expertise, and implemented*  
26 *a comprehensive training and customer experience program.* Our experience in the  
acute care market has demonstrated Tablo’s clinical flexibility and operational  
27 versatility, while also delivering meaningful cost savings to the providers. We plan  
28 to continue leveraging our commercial infrastructure to broaden our installed base in  
the acute care market, as well as driving utilization and fleet expansion with our  
existing customers.

1           38.     The truth continued to emerge on October 12, 2023, when the Company revealed  
2 that revenue growth had been significantly impacted by the FDA’s warning letter. Specifically, the  
3 Company issued a press release announcing preliminary third quarter 2023 financial results, as well  
4 as updated financial guidance for 2023 revenue, which reflected that “[g]rowth in the quarter was  
5 dampened by a larger-than-expected impact in the field from the recent FDA warning letter.” The  
6 press release stated, in relevant part:  
7

8           *Preliminary revenue for the third quarter was \$30.4 million*, a 9% increase over  
9 revenue of \$27.8 million in the third quarter of 2022. *Outset now expects revenue*  
10 *for 2023 to be approximately \$130 million. Preliminary gross margin for the third*  
11 *quarter was 23.6%, or 25.6% on a non-GAAP basis*, compared to 16.4% on a non-  
12 GAAP basis in the third quarter of 2022. Total cash, including restricted cash, cash  
13 equivalents and short-term investments, was \$197 million as of Sept. 30, 2023.

14           “Growth in the quarter was dampened by a larger-than-expected impact in the field  
15 from the recent FDA warning letter, and early signs of a more cautious outlook on  
16 capital spending that we see as a headwind continuing through the fourth quarter,”  
17 said Leslie Trigg, Chair and Chief Executive Officer. “Importantly, we did not see  
18 deals fall out of our pipeline and our economic value proposition remains resonant  
19 and differentiated. Our confidence around generating sustained long-term growth  
20 and reaching profitability remains high.”

21           39.     On this news, the Company’s share price fell \$3.38, or 49.9%, to close at \$3.39 per  
22 share on October 13, 2023, on unusually heavy trading volume.

23           40.     On November 7, 2023, the Company announced its financial results for the third  
24 quarter ended September 30, 2023 in a press release. The press release stated, in relevant part:

25           *Revenue for the third quarter was \$30.4 million*, a 9% increase over revenue of  
26 \$27.8 million in the third quarter of 2022, and gross margin was 23.6%, or 25.6% on  
27 a non-GAAP basis, compared to 16.4% on a non-GAAP basis in the third quarter of  
28 2022.

\*                           \*                           \*

#### **Full Year 2023 Financial Guidance**

Outset reiterated its *2023 revenue guidance of approximately \$130 million and its  
previous gross margin guidance for the year to be in the low-20% range*, exiting  
the fourth quarter in the mid-20% range.



1 \* \* \*

2 **Full Year 2024 Financial Guidance**

3 Outset reaffirmed its previously provided guidance for 2024, including *revenue of*  
4 *\$145 million to \$153 million, growing 12% to 18% over 2023*, and non-GAAP gross  
5 margin in the *low-30% range for 2024*, exiting the year in the mid-30% range for the  
6 fourth quarter.

7 44. On February 21, 2024, the Company filed its annual report for the fiscal year ended  
8 December 31, 2023 on a Form 10-K filed with the SEC, affirming the previously reported financial  
9 results (the “FY23 10-K”). The FY23 10-K stated, in relevant part, the following concerning the  
10 Company’s sales practices:

11 Driving adoption of Tablo in the acute setting has been our primary focus since  
12 Tablo’s clearance by the FDA for use in an acute or chronic care facility in September  
13 2014. *We have invested in growing our economic and clinical evidence, built*  
14 *veteran field service, sales and clinical support teams with significant expertise,*  
15 *and implemented a comprehensive training and customer experience program.*  
16 Our experience in the acute market has demonstrated Tablo’s clinical flexibility and  
17 operational versatility, while also delivering meaningful cost savings to the  
18 providers. *We plan to continue leveraging our commercial infrastructure,*  
19 *including our sales, field service and marketing teams, to broaden our installed*  
20 *base in the acute care market*, as well as driving utilization and fleet expansion with  
21 our existing customers.

22 \* \* \*

23 We primarily sell our solutions through our direct sales organization, which covers  
24 most major metropolitan markets in the United States. *Our sales organization is*  
25 *comprised of our capital sales team, responsible for generating new customer*  
26 *demand for Tablo, and our clinical sales team, responsible for driving utilization*  
27 *and fleet expansion of Tablo at existing customer sites.* In addition, our field service  
28 team provides maintenance services and product support to our customers. Our field  
sales and service teams represent 48% of our total full-time employees as of  
December 31, 2023. The same sales organization and field service team drive Tablo  
penetration in both the acute and home markets. *We believe the ability to leverage*  
*one team to serve both markets will result in significant productivity and cost*  
*optimization as we continue to scale our business.*

45. The FY23 10-K purported to warn of risks to the Company, stating in relevant part:  
*If we fail to retain our sales and marketing personnel, fail to increase our sales*  
*and marketing capabilities or develop broad awareness of Tablo in a cost-effective*  
*manner, we may not be able to generate revenue growth.*

We have limited experience marketing and selling Tablo. We currently rely on our  
direct sales force to sell Tablo in the United States, and *any failure to maintain,*  
*leverage and optimize our direct sales force will negatively affect our business,*  
financial condition and results of operations. The members of our direct sales force  
are highly trained and possess substantial technical expertise, which we believe is  
critical in increasing adoption of Tablo.

1 46. On May 6, 2024, the Company announced that the United States Food and Drug  
2 Administration has granted 510(k) clearance to TabloCart in a press release which stated in relevant  
3 part that “***Outset has resumed distribution of TabloCart with prefiltration and has product***  
4 ***available to ship to customers in the United States.***”

5 47. On May 8, 2024, the Company announced its first quarter 2024 financial results in a  
6 press release which reported quarterly revenue of \$28.2 million, total gross profit of \$8.2 million,  
7 and a net loss of \$39.9 million. The press release provided an optimistic outlook based, in part, on  
8 the recent TabloCart FDA approval, stating in relevant part:

9 “With our ***recent 510(k) clearance for TabloCart with Prefiltration***, 12<sup>th</sup>  
10 consecutive quarter of gross margin expansion and ***strong sales pipeline growth***  
11 ***during the quarter, we are well positioned to capitalize on the \$11 billion U.S.***  
12 ***dialysis market opportunity***,” said Leslie Trigg, Chair and Chief Executive Officer.  
13 “Tablo’s uniquely compelling value proposition continues to resonate with acute-  
14 and home-care providers, with significant new customer wins in both settings during  
15 the quarter.”

13 \* \* \*

#### 14 **Full Year 2024 Financial Guidance**

15 Outset ***reaffirmed its previously provided guidance for 2024*** including revenue of  
16 ***\$145 million to \$153 million, growing 12% to 18% over 2023, and non-GAAP gross***  
17 ***margin in the low-30% range for the full year 2024***, exiting the year in the mid-  
18 30% range for the fourth quarter.

18 48. On May 9, 2024, the Company submitted its quarterly report for the period ended  
19 March 31, 2024 on a Form 10-Q filed with the SEC, affirming the previously reported financial  
20 results. The report stated, in relevant part, the following concerning the Company’s sales practices:

21 Driving adoption of Tablo in the acute care setting has been our primary focus to  
22 date. We have invested in growing our economic and clinical evidence, built a  
23 ***veteran sales and clinical support team with significant expertise, and implemented***  
24 ***a comprehensive training and customer experience program***. Our experience in the  
25 acute care market has demonstrated Tablo’s clinical flexibility and operational  
26 versatility, while also delivering meaningful cost savings to the providers. ***We plan***  
27 ***to continue leveraging our commercial infrastructure to broaden our installed base***  
28 ***in the acute care market, as well as driving utilization and fleet expansion with our***  
***existing customers.***

26 \* \* \*

27 ***We primarily sell our solutions through our direct sales organization***, which covers  
28 most major metropolitan markets in the United States. ***Our sales organization is***  
***comprised of our capital sales team, responsible for generating new customer***  
***demand for Tablo, and our clinical sales team, responsible for driving utilization***



1 **and fleet expansion of Tablo at existing customer sites.** In addition, our field service  
2 team provides maintenance services and product support to our customers. Our field  
3 sales and service teams represent 49% of our total full-time employees as of March  
4 31, 2024. The same sales organization and field service team drive Tablo penetration  
5 in both the acute and home markets. ***We believe the ability to leverage one team to  
6 serve both markets will result in significant productivity and cost optimization as  
7 we continue to scale our business.***

8 49. The above statements identified in ¶¶ 33, 35, 37-38, 40-48 were materially false  
9 and/or misleading, and failed to disclose material adverse facts about the Company’s business,  
10 operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Outset  
11 Medical lacked the sales team and process to execute on the ramp of Tablo sales; (2) that, as a result  
12 of the foregoing, the Company’s revenue growth would be adversely impacted; and (3) that, as a  
13 result of the foregoing, Defendants’ positive statements about the Company’s business, operations,  
14 and prospects were materially misleading and/or lacked a reasonable basis

15 **Disclosures at the End of the Class Period**

16 50. On August 7, 2024, after the market closed, Outset Medical released its second  
17 quarter 2024 financial results, significantly missing consensus estimates and lowering its full year  
18 2024 outlook, reducing its full year 2024 revenue guidance by \$39 million at the midpoint. The  
19 press release disclosed the Company would be forced to take “clear steps to improve our execution.”  
20 Specifically, the press release reported, in relevant part:

21 [N]ew console placements were below our expectations and will be ***lower than we  
22 originally forecasted for the year. We are taking clear steps to improve our  
23 execution*** and grow the business over the long term to bring the benefits of Tablo to  
24 even more providers and dialysis patients.

25 \* \* \*

26 **Second Quarter 2024 Financial Results**

27 ***Revenue for the second quarter was \$27.4 million*** compared to \$36.0 million in the  
28 second quarter of 2023, driven by a decline in product revenue to \$19.2 million.  
Service and other revenue was \$8.2 million, an increase of 21.5% compared to \$6.7  
million in the second quarter of 2023. Recurring revenue from the sale of Tablo  
cartridges and service increased by 24% as compared to the prior-year period.

***Total gross profit was \$9.8 million***, compared to \$7.7 million for the second quarter  
of 2023. Total gross margin was 35.7%, compared to 21.4% in the second quarter of  
2023.

\* \* \*



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

8 55. Plaintiff's claims are typical of the claims of the members of the Class as all members  
9 of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that  
10 is complained of herein.

11 56. Plaintiff will fairly and adequately protect the interests of the members of the Class  
12 and has retained counsel competent and experienced in class and securities litigation.

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

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

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

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

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

28

1 **UNDISCLOSED ADVERSE FACTS**

2 59. The market for Outset Medical’s securities was open, well-developed and efficient  
3 at all relevant times. As a result of these materially false and/or misleading statements, and/or  
4 failures to disclose, Outset Medical’s securities traded at artificially inflated prices during the Class  
5 Period. Plaintiff and other members of the Class purchased or otherwise acquired Outset Medical’s  
6 securities relying upon the integrity of the market price of the Company’s securities and market  
7 information relating to Outset Medical, and have been damaged thereby.

8 60. During the Class Period, Defendants materially misled the investing public, thereby  
9 inflating the price of Outset Medical’s securities, by publicly issuing false and/or misleading  
10 statements and/or omitting to disclose material facts necessary to make Defendants’ statements, as  
11 set forth herein, not false and/or misleading. The statements and omissions were materially false  
12 and/or misleading because they failed to disclose material adverse information and/or  
13 misrepresented the truth about Outset Medical’s business, operations, and prospects as alleged  
14 herein.

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

26 **LOSS CAUSATION**

27 62. Defendants’ wrongful conduct, as alleged herein, directly and proximately caused  
28 the economic loss suffered by Plaintiff and the Class.



1 Class Period, Defendants made or caused to be made a series of materially false and/or misleading  
2 statements about Outset Medical's business, prospects, and operations. These material  
3 misstatements and/or omissions created an unrealistically positive assessment of Outset Medical  
4 and its business, operations, and prospects, thus causing the price of the Company's securities to be  
5 artificially inflated at all relevant times, and when disclosed, negatively affected the value of the  
6 Company shares. Defendants' materially false and/or misleading statements during the Class Period  
7 resulted in Plaintiff and other members of the Class purchasing the Company's securities at such  
8 artificially inflated prices, and each of them has been damaged as a result.

9 67. At all relevant times, the market for Outset Medical's securities was an efficient  
10 market for the following reasons, among others:

11 (a) Outset Medical shares met the requirements for listing, and was listed and  
12 actively traded on the NASDAQ, a highly efficient and automated market;

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

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

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

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



1 **FIRST CLAIM**

2 **Violation of Section 10(b) of The Exchange Act and**

3 **Rule 10b-5 Promulgated Thereunder**

4 **Against All Defendants**

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

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

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

20 74. Defendants, individually and in concert, directly and indirectly, by the use, means or  
21 instrumentalities of interstate commerce and/or of the mails, engaged and participated in a  
22 continuous course of conduct to conceal adverse material information about Outset Medical's  
23 financial well-being and prospects, as specified herein.

24 75. Defendants employed devices, schemes and artifices to defraud, while in possession  
25 of material adverse non-public information and engaged in acts, practices, and a course of conduct  
26 as alleged herein in an effort to assure investors of Outset Medical's value and performance and  
27 continued substantial growth, which included the making of, or the participation in the making of,  
28 untrue statements of material facts and/or omitting to state material facts necessary in order to make



1 the statements made about Outset Medical and its business operations and future prospects in light  
2 of the circumstances under which they were made, not misleading, as set forth more particularly  
3 herein, and engaged in transactions, practices and a course of business which operated as a fraud  
4 and deceit upon the purchasers of the Company's securities during the Class Period.

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

17         77. Defendants had actual knowledge of the misrepresentations and/or omissions of  
18 material facts set forth herein, or acted with reckless disregard for the truth in that they failed to  
19 ascertain and to disclose such facts, even though such facts were available to them. Such defendants'  
20 material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose  
21 and effect of concealing Outset Medical's financial well-being and prospects from the investing  
22 public and supporting the artificially inflated price of its securities. As demonstrated by Defendants'  
23 overstatements and/or misstatements of the Company's business, operations, financial well-being,  
24 and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the  
25 misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by  
26 deliberately refraining from taking those steps necessary to discover whether those statements were  
27 false or misleading.

28



1 positions and their ownership and contractual rights, participation in, and/or awareness of the  
2 Company's operations and intimate knowledge of the false financial statements filed by the  
3 Company with the SEC and disseminated to the investing public, Individual Defendants had the  
4 power to influence and control and did influence and control, directly or indirectly, the decision-  
5 making of the Company, including the content and dissemination of the various statements which  
6 Plaintiff contends are false and misleading. Individual Defendants were provided with or had  
7 unlimited access to copies of the Company's reports, press releases, public filings, and other  
8 statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were  
9 issued and had the ability to prevent the issuance of the statements or cause the statements to be  
10 corrected.

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

15 85. As set forth above, Outset Medical and Individual Defendants each violated Section  
16 10(b) and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their  
17 position as controlling persons, Individual Defendants are liable pursuant to Section 20(a) of the  
18 Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other  
19 members of the Class suffered damages in connection with their purchases of the Company's  
20 securities during the Class Period.

21 **PRAYER FOR RELIEF**

22 WHEREFORE, Plaintiff prays for relief and judgment, as follows:

23 (a) Determining that this action is a proper class action under Rule 23 of the Federal  
24 Rules of Civil Procedure;

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

1 (c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this  
2 action, including counsel fees and expert fees; and

3 (d) Such other and further relief as the Court may deem just and proper.

4 **JURY TRIAL DEMANDED**

5 Plaintiff hereby demands a trial by jury.

6 DATED:

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