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

_____, individually and on behalf of all
others similarly situated,

Plaintiff,

v.

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

Defendants.

Case No.
**COMPLAINT FOR VIOLATIONS OF
THE FEDERAL SECURITIES LAWS**

CLASS ACTION

DEMAND FOR JURY TRIAL

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

11 **NATURE OF THE ACTION**

12 1. This is a federal securities class action on behalf of all persons or entities who
13 purchased or otherwise acquired Outset securities between September 15, 2020, and August 7,
14 2024, inclusive (the “Class Period”) against the Defendants seeking to pursue remedies under the
15 Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.* (the “Exchange Act”) and the rules and
16 regulations promulgated thereunder, including Rule 10b-5, 17 C.F.R. § 240.10b-5 (“Rule 10b-
17 5”).

18 2. Outset is a medical technology company focused on kidney dialysis, the primary
19 treatment for acute and chronic kidney failure. The Company’s flagship product is the Tablo
20 Hemodialysis System (“Tablo”). Tablo is a dialysis machine that purifies tap water and then
21 artificially purifies and removes toxins from the blood of patients suffering from kidney failure.
22 In October 2022, Outset introduced the TabloCart with Prefiltration (“TabloCart”) as an accessory
23 for the Tablo, intended to provide additional maneuverability and pre-filtration capabilities for
24 poor water qualities.

25 3. Tablo is cleared by the U.S. Food and Drug Administration (“FDA”) for use in the
26 hospital, clinic or home setting. Tablo is not cleared by the FDA for Continuous Renal
27 Replacement Therapy (“CRRT”), in which solute removal and fluid balance is managed
28 continuously over 24 hours in a hospital.

1 4. On July 7, 2023, after market hours, Outset disclosed that it had received a
2 Warning Letter from the FDA which “assert[ed] that certain materials ... on the Company’s
3 website promote continuous renal replacement therapy (CRRT), a modality outside of the current
4 indications for the Tablo® Hemodialysis System” and asserted that TabloCart “requires prior
5 510(k) clearance for marketing authorization.”

6 5. On this news, Outset’s stock price fell \$1.20, or 5.9%, to close at \$19.26 per share
7 on July 10, 2023.

8 6. On August 2, 2023, after market hours, Outset announced that it had paused the
9 shipment of TabloCart pending the FDA’s 510(k) clearance.

10 7. On this news, Outset’s stock price fell \$1.97, or 10.2%, to close at \$17.39 per share
11 on August 3, 2023.

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

17 9. On this news, the Company’s share price fell \$3.38, or 49.9%, to close at \$3.39
18 per share on October 13, 2023.

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

25 11. On this news, the Company’s share price fell \$2.33, or 68.5%, to close at \$1.07
26 per share on August 8, 2024.

27 12. Throughout the Class Period, Defendants made materially false and/or misleading
28 statements, as well as failed to disclose material adverse facts about the Company’s business,

1 operations and prospects. Specifically, Defendants failed to disclose to investors that: (1) the
2 TabloCart would require prior 510(k) clearance from the FDA for marketing authorization;
3 (2) the Company had not obtained the required FDA clearance to market and sell the TabloCart;
4 (3) as such, Outset would be forced to halt shipment of the TabloCart; (4) Outset had promoted
5 continuous renal replacement therapy (or CRRT) as a modality within the FDA-approved
6 indications for the Tablo, which was not the case; (5) Outset lacked the sales team and process to
7 execute on the ramp of Tablo sales; (6) the Company's internal controls were inadequate and
8 resulted in the improper marketing of Tablo and TabloCart and that the Company's SOX
9 certifications were false and misleading when made; (7) the Company's reports and financial
10 statements did not fairly present in all material respects the financial condition, including the
11 reliance on improper marketing, that the revenue and growth reported therein was the result of
12 undisclosed, illicit and unsustainable improper marketing; and (8) as a result of the foregoing,
13 Defendants' positive statements about the Company's business, operations and prospects were
14 materially misleading and/or lacked a reasonable basis.

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

18 **JURISDICTION AND VENUE**

19 14. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange
20 Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC
21 (17 C.F.R. § 240.10b-5).

22 15. This Court has jurisdiction over the subject matter of this action pursuant to
23 28 U.S.C. § 1331, Section 27 of the Exchange Act (15 U.S.C. § 78aa). This Court has jurisdiction
24 over Defendants because each Defendant has sufficient minimum contacts with this district,
25 particularly since Outset's principal place of business is in this District.

26 16. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b), Section 27 of the
27 Exchange Act (15 U.S.C. § 78aa). Substantial acts in furtherance of the alleged fraud or the
28 effects of the fraud have occurred in this Judicial District. Many of the acts and omissions charged

1 herein, including the dissemination of materially false and misleading information to the investing
2 public, and the omission of material information, occurred in substantial part in this District.

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

7 **DIVISIONAL ASSIGNMENT**

8 18. Pursuant to Northern District of California Civil Local Rules 3-2(c) and 3-5(b)
9 assignment to the San Jose Division of this district is proper because a substantial part of the
10 events or omissions, which give rise to the claims asserted herein, occurred in Santa Clara County,
11 California and Outset's principal place of business is located, in San Jose, California.

12 **PARTIES**

13 19. As set forth in its Certification attached as Exhibit A, Plaintiff purchased Outset
14 securities during the Class Period and was damaged as a result.

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

18 21. Defendant Leslie L. Trigg ("Trigg") has served as Outset's Chief Executive
19 Officer ("CEO") at all relevant times and was elected as Chair of Outset's Board of Directors in
20 2022.

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

27 23. Defendant Rebecca Chambers ("Chambers") was Outset's CFO at all relevant
28 times until July 16, 2021. In a Form 8-K filed with the SEC on July 1, 2021, the Company

1 announced Chambers notified the Company on June 28, 2021, of her decision to resign from
2 Outset effective July 16, 2021.

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

15 **SUBSTANTIVE ALLEGATIONS**

16 **Background**

17 25. Outset was founded in 2003 and is headquartered in San Jose, California. In 2014,
18 Tablo was cleared for use in patients with acute and/or chronic renal failure, with or without
19 ultrafiltration, in the settings of an acute or chronic care facility under Section 510(k) of the
20 Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 C.F.R. § 807.81(a). In March 2020, Tablo
21 was cleared for home use under Section 510(k) of the FDCA.

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

27 27. In the 510(k) clearance process, before a device may be marketed, the FDA must
28 determine that a proposed device is substantially equivalent to a legally marketed predicate

1 device, which includes a device that has been previously cleared through the 510(k) process, a
2 device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that
3 was originally on the U.S. market pursuant to an approved Premarket Approval (“PMA”) and
4 later down-classified, or a 510(k)-exempt device. To be substantially equivalent, the proposed
5 device must have the same intended use as the predicate device, and either have the same
6 technological characteristics as the predicate device or have different technological characteristics
7 and not raise different questions of safety or effectiveness than the predicate device. Clinical data
8 are sometimes required to support substantial equivalence. The FDA’s 510(k) clearance process
9 usually takes from three to twelve months but can last longer.

10 28. Educational and promotional activities and training methods must comply with
11 FDA and other applicable laws. These laws include the prohibition of the promotion of a medical
12 device for a use that has not been cleared or approved by the FDA. Use of a device outside of its
13 cleared or approved indications is known as “off-label” use. If the FDA determines that
14 educational and promotional activities or training constitutes promotion of an off-label use, it may
15 request that a company modify its training or promotional materials or subject the company to
16 regulatory or enforcement actions, including the issuance of warning letters, untitled letters, fines,
17 penalties, injunctions or seizures. It is also possible that other federal, state or foreign
18 enforcement authorities might take action if they consider educational and promotional activities
19 or training methods to constitute promotion of an off-label use, which could result in significant
20 fines or penalties under other statutory authorities, such as laws prohibiting false claims for
21 reimbursement.

22 29. Outset commenced an initial public offering (“IPO”) on or about September 15,
23 2020, selling 10.29 million shares of common stock to the public at a price of \$27 per share. In
24 connection with the IPO, the Company filed a Registration Statement on Form S-1 on August 21,
25 2024, Amendment No. 1 to the Registration Statement on Form S-1/A on September 9, 2020,
26 and a Form S-1MEF on September 14, 2020 (together, the “Registration Statement”). On
27 September 16, 2024, the Company file a Prospectus on Form 424B4 (the “IPO Prospectus”)
28

1 (together, the Registration Statement and IPO Prospectus are the “IPO Offering Documents”).
2 Defendants Trigg and Chambers signed the IPO Offering Documents.

3
4 **Defendants’ Materially False and Misleading
Statements Issued During the Class Period**

5 30. The Class Period begins on September 15, 2020, when Outset’s common stock
6 began trading on the Nasdaq Global Select Market. In the IPO Offering Documents, the Company
7 touted Tablo as a “dialysis clinic on wheels and allows providers to standardize to a single
8 technology platform from the hospital to the home.” The Company stated, in relevant part, that:

9 Our technology is designed to elevate the dialysis experience for patients, and help
10 providers overcome traditional care delivery challenges. Requiring only an
11 electrical outlet and tap water to operate, Tablo frees patients and providers from
12 the burdensome infrastructure required to operate traditional dialysis machines.
The integration of water purification and on-demand dialysate production enables
Tablo to serve as a dialysis clinic on wheels and allows providers to standardize to
a single technology platform from the hospital to the home.

13 31. The Company also represented that “Tablo is currently cleared by the United
14 States Food and Drug Administration (FDA) for use in the hospital, clinic or home setting,” and
15 that its “policy is to refrain from statements that could be considered off-label promotion of
16 Tablo.” The Company repeated these representations in its Quarterly Report on Form 10-Q
17 (“Form 10-Q”) for the quarterly period ended September 30, 2020 filed with the SEC on
18 November 12, 2020 (“Q3 2020 Form 10-Q”) (signed by Trigg and Chambers), Annual Report on
19 Form 10-K (“Form 10-K”) for fiscal year ended (“fye”) December 31, 2020 filed with the SEC
20 on March 22, 2021 (“2020 Form 10-K”) (signed by Trigg and Chambers); Form 10-K for fye
21 December 31, 2021 (“2021 Form 10-K”) filed with the SEC on February 23, 2022 (signed by
22 Trigg and Ahmed); Form 10-K for fye December 31, 2022 (“2022 Form 10-K”) filed with the
23 SEC on February 13, 2023 (signed by Trigg and Ahmed).

24 32. In the IPO Offering Documents and its 2020 Form 10-K filed on March 22, 2021,
25 Outset also touted “Tablo is the first and only fully integrated hemodialysis system that can be
26 used to deliver treatment across all care settings from the ICU to home.”

27 33. On November 11, 2020, the Company issued a press release announcing third
28 quarter results and stating that it had “[r]ecorded net revenue of \$13.8 million in the third quarter

1 of 2020, a 423% increase compared to \$2.6 million in the third quarter of 2019.” In the press
2 release Defendant Trigg stated, “Our commercial momentum continued to accelerate in the third
3 quarter as we signed new contracts with some of the largest national and regional health systems
4 in the country.”

5 34. On November 12, 2020, the Company filed its Q3 2020 Form 10-Q for the third
6 quarter of 2020, which included Certifications Pursuant to Section 302 of the Sarbanes-Oxley Act
7 of 2002 (“SOX Certifications”) signed by Defendants Trigg and Chambers, respectively, which
8 stated:

- 9 1. I have reviewed this Quarterly Report on Form 10-Q of Outset
10 Medical, Inc.;
- 11 2. Based on my knowledge, this report does not contain any untrue
12 statement of a material fact or omit to state a material fact necessary
13 to make the statements made, in light of the circumstances under
14 which such statements were made, not misleading with respect to
15 the period covered by this report;
- 16 3. Based on my knowledge, the financial statements, and other
17 financial information included in this report, fairly present in all
18 material respects the financial condition, results of operations and
19 cash flows of the registrant as of, and for, the periods presented in
20 this report;
- 21 4. The registrant’s other certifying officer(s) and I are responsible for
22 establishing and maintaining disclosure controls and procedures (as
23 defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and
24 internal control over financial reporting (as defined in Exchange Act
25 Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
- 26 (a) designed such disclosure controls and procedures, or caused
27 such disclosure controls and procedures to be designed under
28 our supervision, to ensure that material information relating
to the registrant, including its consolidated subsidiaries, is
made known to us by others within those entities,
particularly during the period in which this report is being
prepared;
- (b) designed such internal control over financial reporting, or
caused such internal control over financial reporting to be
designed under our supervision, to provide reasonable
assurance regarding the reliability of financial reporting and
the preparation of financial statements for external purposes
in accordance with generally accepted accounting
principles;
- (c) evaluated the effectiveness of the registrant’s disclosure
controls and procedures and presented in this report our
conclusions about the effectiveness of the disclosure

1 controls and procedures, as of the end of the period covered
by this report based on such evaluation; and

2 (d) disclosed in this report any change in the registrant's internal
3 control over financial reporting that occurred during the
4 registrant's most recent fiscal quarter (the registrant's fourth
5 fiscal quarter in the case of an annual report) that has
materially affected, or is reasonably likely to materially
affect, the registrant's internal control over financial
reporting; and

6 5. The registrant's other certifying officer(s) and I have disclosed,
7 based on our most recent evaluation of internal control over
8 financial reporting, to the registrant's auditors and the audit
committee of the registrant's board of directors (or persons
performing the equivalent functions):

9 (a) all significant deficiencies and material weaknesses in the
10 design or operation of internal control over financial
11 reporting which are reasonably likely to adversely affect the
registrant's ability to record, process, summarize and report
financial information; and

12 (b) any fraud, whether or not material, that involves
13 management or other employees who have a significant role
in the registrant's internal control over financial reporting.

14 35. Outset filed signed SOX Certifications with all of its quarterly reports filed on
15 Form 10-Q and annual reports filed on Form 10-K with the SEC during the Class Period.
16 Defendants Trigg signed all SOX Certifications during the Class Period. Defendant Chambers
17 signed SOX Certifications from the beginning of the Class Period until May 5, 2021. Defendant
18 Ahmed signed all SOX Certifications from August 5, 2021 until the end of the Class Period.

19 36. On March 9, 2021, the Company issued a press release announcing fourth quarter
20 and full-year results and stating that it had "[r]ecorded net revenue of \$17.2 million in the fourth
21 quarter and \$49.9 million for the full year of 2020, representing 143% and 231% increases
22 respectively, over the corresponding periods of 2019." In the press release, Defendant Trigg
23 stated, "In the fourth quarter our team continued to outperform while building a solid foundation
24 for growth through 2021 and beyond."

25 37. On May 5, 2021, the Company issued a press release announcing first quarter
26 results and stating, "[r]ecorded net revenue of \$22.9 million in the first quarter of 2021, a 219%
27 increase compared to \$7.2 million in the first quarter of 2020." In the press release, Defendant
28 Trigg stated, "Our first quarter was marked by strong revenue performance, continued operational

1 execution, and substantial progress across our strategic initiatives, ... Demand for Tablo is both
2 increasing and extending beyond the acute and subacute care settings, with a growing number of
3 customers preparing for home care programs. With strong interest in Tablo, a robust backlog and
4 clear visibility on the timing of console placements, we are confident in our positioning for
5 consistent strong performance in 2021 and beyond.”

6 38. On August 5, 2021, the Company issued a press release announcing second quarter
7 results and stating “[r]ecorded net revenue of \$25.2 million in the second quarter of 2021, a 115%
8 increase compared to \$11.7 million in the second quarter of 2020.” In the press release, Defendant
9 Trigg stated, “In the first half of 2021, we delivered best-in-class revenue growth and steady gross
10 margin improvement driven by a team that is dedicated to, and united around, transforming the
11 dialysis experience for patients and providers, ... With new home console bookings up
12 substantially in the second quarter, and both current and new customers purchasing Tablo for
13 acute use, our integrated commercial strategy is working as expected. We remain confident in
14 our ability to execute on each of our key strategic initiatives for 2021 and in our long-term growth
15 prospects.”

16 39. On November 3, 2021, the Company issued a press release announcing third
17 quarter financial results and stating, “[r]ecorded net revenue of \$26.3 million in the third quarter
18 of 2021, a 91.3% increase compared to \$13.8 million in the third quarter of 2020.” In the press
19 release, Defendant Trigg stated, “Our strong third quarter performance further reinforces our
20 confidence in our business and in our expectations for growth.”

21 40. In the Company’s 2021 ESG Report dated November 7, 2021, the Company
22 stated:

23 Outset has adopted a promotional material procedure to define acceptable and
24 unacceptable advertising, sales support, training, and other promotional practices
25 for Outset medical devices in the United States. Included in this procedure is
26 Outset’s policy that all claims with respect to Outset products must be consistent
27 with approved labeling, with the data submitted to the FDA to obtain 510(k)
28 clearance and/or substantiated with appropriate evidence (*i.e.*, instructions-for-use,
verification and validation testing, clinical study report, or any other report
requiring a similar rigorous process of review and approval). In addition, without
exception, promotional material may be neither false nor misleading (either in
terms of a specific product claim or the overall net impression conveyed by the
promotional material) and must comply with all specific conditions of approval for
the product being promoted. Furthermore, promotional materials for a cleared or

1 approved product may not promote, discuss, or refer to uncleared, unapproved, or
off-label use.

2 41. On February 16, 2022, the Company issued a press release reporting fourth quarter
3 results and stating, “[r]ecorded net revenue of \$28.2 million in the fourth quarter of 2021, a 63.2%
4 increase compared to \$17.2 million in the fourth quarter of 2020, and \$102.6 million for the full
5 year of 2021, representing an increase of 105.5% compared to \$49.9 million for 2020.” In the
6 press release, Defendant Trigg stated, “Our entire team contributed to an exceptional 2021,
7 driving record revenue growth, meaningful progress toward our long-term gross margin goal and
8 excellent visibility into 2022 ... Our established relationships with 7 of the 8 largest national
9 health systems and one-third of the largest 100 regional health systems puts us in a strong position
10 for growth this year in both the acute and home settings.”

11 42. On May 4, 2022, the Company issued a press release reporting first quarter results
12 and stating, “[r]ecorded net revenue of \$30.6 million in the first quarter of 2022, a 33.3% increase
13 compared to \$22.9 million in the first quarter of 2021 and an 8.5% increase compared to \$28.2
14 million in the fourth quarter of 2021.” In the press release, Defendant Trigg stated, “The first
15 quarter of 2022 was marked by strong revenue growth and gross margin expansion, which
16 resulted from the momentum we see among both acute care customers and providers expanding
17 access to Tablo at Home, ... As interest for Tablo accelerates across all market segments, we
18 continued to expand gross margins, invest in innovation, and deliver consistent and predictable
19 financial and operational results, increasing our confidence for sustained strong performance
20 through 2022 and beyond.”

21 43. On August 1, 2022, the Company issued a press release reporting “[r]evenue for
22 the second quarter totaled \$25.1 million, in line with guidance provided on June 13, 2022.” In
23 the press release, Defendant Trigg stated, “[a]s we look to the second half of the year, we see no
24 change in underlying demand for Tablo.”

25 44. In the same August 1, 2022 press release, the Company announced that it had
26 resumed shipment of Tablo Systems for home use because the FDA had approved its 510(k)
27 submission. In a press release, the Company stated, in relevant part:

28 Outset Medical, Inc. (Nasdaq: OM) (“Outset” or the “Company”), a medical
technology company pioneering a first-of-its-kind technology to reduce the cost

1 and complexity of dialysis, today announced clearance by the Food and Drug
2 Administration of its previously disclosed 510(k) submission and resumption of
3 Tablo® Hemodialysis System shipments for home use.

4 The Company also reported financial results for the second quarter ended June 30,
5 2022 and provided financial guidance for 2022. Revenue for the second quarter
6 totaled \$25.1 million, in line with guidance provided on June 13, 2022. Gross
7 margin for the second quarter was 15.1%, compared to 4.2% in the second quarter
8 of 2021 and 14.5% in the first quarter of 2022.

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

16 45. On August 2, 2022, the Company filed with the SEC its Form 10-Q for the fiscal
17 period ended June 30, 2022 (“Q2 2022 Form 10-Q”), affirming the previously reported financial
18 results. The report stated the following regarding the Company’s sales practices and FDA
19 approval:

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

22 Driving adoption of Tablo in the acute care setting has been our primary focus to
23 date. We have invested in growing our economic and clinical evidence, built a
24 veteran sales and clinical support team with significant expertise, and implemented
25 a comprehensive training and customer experience program. Our experience in the
26 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.

46. On November 8, 2022, the Company issued a press release reporting third quarter
financial results and stating

- Recorded net revenue of \$27.8 million in the third quarter of 2022, a 5.5% increase compared to \$26.3 million in the third quarter of 2021 and a 10.8% increase compared to \$25.1 million in the second quarter of 2022
- Achieved gross margin for the third quarter of 2022 of 15.6%, compared to 11.2% in the third quarter of 2021 and 15.1% in the second quarter of 2022
- Resumed shipments to new home patients, and grew the Tablo home patient base beyond initial expectations for the third quarter

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

* * *

Full Year 2022 Financial Guidance

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

47. In the press release, Defendant Trigg stated, “Our third quarter results reflect the value Tablo is delivering in both the acute and home settings, with console shipments exceeding our initial expectations ... we believe our continued expansion in the acute setting and our strong start to rebuilding the home patient pipeline reflects patient preference for Tablo and strong demand across end markets.”

48. Also, on November 8, 2022, during an earnings call regarding the Company’s third quarter 2022 financial results, Defendant Trigg announced the addition of the TabloCart to Outset’s line of products, stating:

To that end, we are pleased to introduce TabloCart, which is a new accessory for Tablo. TabloCart provides additional maneuverability around the hospital and incremental pre-filtration capabilities for sites that suffer from water quality that is far worse than the national drinking water standards. TabloCart will be sold separately at an expected margin accretive ASP. We closed Q3 exceeding our internal projections for TabloCart orders indicating strong early demand for this innovative accessory.

In summary, our strong Q3 was driven by significant expansion in the acute setting and a home pipeline that is rebuilding ahead of expectations. It is clear to us that Tablo remains a highly differentiated solution in one of the largest, most expensive recession proof areas of healthcare. Our performance reflects the truly incredible Outset team who I would like to thank for their courage, commitment, and conviction in all they do every day to advance our mission.

49. On November 9, 2022, the Company filed with the SEC its Form 10-Q for the fiscal period ended September 30, 2022 (“Q3 2022 Form 10-Q”), affirming the previously reported financial results. The report stated the following regarding the Company’s sales practices and FDA approval:

In May 2022, we implemented a shipment hold on the distribution and marketing of Tablo for use in the home environment pending the FDA’s review and clearance of a 510(k) application we submitted for changes made since the device’s original March 2020 clearance.

* * *

1
2 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.

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

6 50. On January 9, 2023, the Company issued a press release announcing preliminary
7 financial results for fourth quarter and fiscal year ended December 31, 2022, as well as guidance
8 for fiscal 2023, stating in relevant part:

- 9
- 10 • Revenue in the fourth quarter is expected to be approximately \$31.5 million,
a 13% increase compared to \$27.8 million in the third quarter of 2022
 - 11 • Revenue for 2022 is expected to be approximately \$115 million, a 12%
increase compared to \$102.6 million in 2021
 - 12 • Period-end installed base increased 54% year-over-year to approximately
13 4,000 Tablo® Hemodialysis Systems, including 3,200 with acute- and sub-
acute care providers and a more than doubling of units with home providers
14 to nearly 800

* * *

15
16 Outset expects 2023 revenue to be between \$140 million to \$150 million, growing
approximately 22% to 30% over expected revenue for 2022. Non-GAAP gross
17 margin is expected to expand to approximately 20% for the full year 2023 and exit
the year in the mid-20% range for the fourth quarter of 2023.

18 51. On February 13, 2023, the Company issued a press release announcing the
19 Company's financial results for the fourth quarter and year ended December 31, 2022,
20 stating in relevant part:

- 21
- 22 • Recorded net revenue of \$32.0 million in the fourth quarter, a 15.3%
increase compared to \$27.8 million in the third quarter, and a 14.0%
23 increase compared to \$28.2 million in the fourth quarter of 2021. Revenue
for the full year was \$115.4 million, an increase of 12.4% compared to
\$102.6 million in 2021
 - 24 • Achieved gross margin for the fourth quarter of 16.5% (17.1% on a non-
25 GAAP basis), compared to 11.8% (12.0% on a non-GAAP basis) in the
fourth quarter of 2021. Gross margin for the full year was 15.5% (16.1%
26 on a non-GAAP basis), an increase of more than 800 basis points over 2021

* * *

27
28 **Full Year 2023 Financial Guidance**

1 Outset reaffirmed its previously provided guidance for 2023, including revenue of
2 \$140 million to \$150 million, growing approximately 22% to 30% over 2022, and
non-GAAP gross margin of approximately 20% for 2023, exiting the year in the
mid-20% range for the fourth quarter.

3 52. On February 13, 2023, the Company filed its 2022 Form 10-K with the SEC,
4 affirming the previously reported financial results. The report stated the following regarding the
5 TabloCart and the Company's sales practices:

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

8 * * *

9 The Tablo system is comprised of the following components:

10 * * *

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

13 * * *

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

17 * * *

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

21 * * *

22 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.

23 53. During an earnings call on February 13, 2023, Defendant Trigg stated:
24

25 From a product innovation perspective, last quarter was our first full quarter in
market with TabloCart, a new accessory that provides additional maneuverability
26 around the hospital and incremental pre-filtration capabilities for sites with water
quality that is far worse than the national drinking water standards. As a reminder,
27 TabloCart is sold separately at a gross margin accretive ASP. Since its launch in
Q3, we've been pleased with the strong demand and positive reaction from
28 customers.

1 54. During the same earnings call, Defendant Ahmed stated:

2 Our fourth quarter revenue increased approximately 15.3% sequentially and 13.7%
3 year-over-year to \$32 million with a year-over-year change driven primarily by
4 higher consumables revenue and higher service and other revenue. This uptick in
recurring revenue is one of the benefits of our expanded installed base and
continues to be one of the key drivers of gross margin expansion.

5 Product revenue was up 21.3% from the prior quarter and increased 11.5% year-
6 over-year to \$26.4 million. Console revenue grew 22.8% from the third quarter
7 and increased by 1.5% year-over-year to \$18.4 million. We saw console ASPs
8 increase again year-over-year, driven primarily by the ongoing demand for Tablo
9 XT and by demand TabloCart, our new accessory launched in the fourth quarter of
2022.

10 * * *

11 [W]e have absolutely seen ASP increases from the XT attach, which is again adding
12 value to our customers instead of monetizing that value, which we like. We've also
13 seen TabloCart be a big driver or be a driver rather of ASP sort of lift in the quarter
14 here and are really pleased with the performance there.

15 The one thing, we have also talked a lot about the fact that we haven't had to
16 discount very heavily in our past, which we view as again, a testament to Tablo's
17 economic value proposition. So pricing, we have no complaints about pricing and
18 pricing is favorable, works favorably for us.

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

- 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
24 compared to \$32.0 million in the fourth quarter of 2022
- 25 • Achieved gross margin for the first quarter of 19.2% (20.3% on a non-
26 GAAP basis), compared to 14.5% (14.8% on a non-GAAP basis) in the first
27 quarter of 2022

28 * * *

29 **Full Year 2023 Financial Guidance**

30 Outset now projects revenue for 2023 to range from \$144 million to \$150 million,
31 which represents approximately 25% to 30% growth over the Company's fiscal
32 year 2022 revenue. This updated guidance compares to prior 2023 revenue
33 guidance of \$140 million to \$150 million. In addition, the Company expects gross
34 margin for the year to be in the low-20% range, up from its prior guidance of
35 approximately 20%, and exiting the fourth quarter in the mid-20% range.

36 56. On May 3, 2023, during an earning call, Defendant Trigg stated:

1 Another important element of our commercial strategy is to drive utilization across
2 the installed base, and we were pleased to see positive trends in treatment volume
3 during the quarter, in line with our expectations. We also saw ASPs rise, both on
4 consoles and consumables, which serves as strong validation of Tablo's clinical and
5 economic value proposition versus our competitors. Our ASPs benefited again
6 from better-than-expected uptake of Tablo add-ons, including good early demand
7 for our TabloCart new product accessory.

8 * * *

9 From a product innovation standpoint, we are very pleased with demand for
10 TabloCart, a new product accessory we introduced in Q3 of last year that provides
11 additional maneuverability around the hospital, and incremental water prefiltration
12 capabilities. TabloCart is sold separately and is gross margin accretive ASP and is
13 proving to be a valuable solution to many of our acute care customers.

14 57. On May 4, 2023, the Company filed with the SEC its Form 10-Q for the period
15 ended March 31, 2023 (“Q1 2023 Form 10-Q”), affirming the previously reported financial
16 results. The report stated the following regarding the Company’s sales practices:

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

18 * * *

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

21 * * *

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

27 * * *

28 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.

58. In the Company’s 2023 ESG Report dated June 30, 2023, the Company stated:

Outset has adopted an ethical marketing procedure that defines acceptable and
unacceptable advertising, sales support, training, and other promotional practices
for Outset medical devices in the United States. Included in this procedure is
Outset’s policy that all claims with respect to Outset products must be consistent
with approved labeling, with the data submitted to the FDA to obtain 510(k)
clearance and/or substantiated with appropriate evidence (*i.e.*, instructions-for-use,
verification and validation testing, clinical study report, or any other report
requiring a similar rigorous process of review and approval).

In addition, without exception, promotional material or statements made by Outset
sales representatives may not promote, discuss, or refer to uncleared, unapproved,

1 or off-label use. This means that all promotional activities may be neither false nor
2 misleading (either in terms of a specific product claim or the overall net impression
conveyed by the promotional material) and must comply with all specific
conditions of approval for the product being promoted.

3 59. The above statements identified in ¶¶ 30-58 were materially false and/or
4 misleading and failed to disclose material adverse facts about the Company's business,
5 operations, and prospects. Specifically, Defendants failed to disclose to investors that: (1) the
6 TabloCart would require prior 510(k) clearance from the FDA for marketing authorization;
7 (2) the Company had not obtained the required FDA clearance to market and sell the TabloCart;
8 (3) as such, Outset would be forced to halt shipment of the TabloCart; (4) Outset had promoted
9 continuous renal replacement therapy (or CRRT) as a modality within the FDA-approved
10 indications for the Tablo, which was not the case; (5) Outset lacked the sales team and process to
11 execute on the ramp of Tablo sales; (6) the Company's internal controls were inadequate and
12 resulted in the improper marketing of TabloCart and improper promotion of Tablo for CRRT and
13 that the Company's SOX certifications were false and misleading when made; (7) the Company's
14 reports and financial statements did not fairly present in all material respects the financial
15 condition, including the reliance on improper marketing, that the revenue and growth reported
16 therein was the result of undisclosed, illicit and unsustainable improper marketing; and (8) as a
17 result of the foregoing, Defendants' positive statements about the Company's business,
18 operations, and prospects were materially misleading and/or lacked a reasonable basis.

19 **The Truth Begins To Be Revealed**

20 60. The truth began to emerge on July 7, 2023, after market hours, when Outset
21 disclosed that it had received a Warning Letter from the FDA. Specifically, the Company filed a
22 Form 8-K with the SEC disclosing:

23 On July 6, 2023, Outset Medical, Inc. (the "Company") received a Warning Letter,
24 dated July 5, 2023 (the "Warning Letter"), from the United States Food and Drug
Administration (the "FDA").

25 As previously disclosed by the Company in its Annual Report on Form 10-K filed
26 on February 13, 2023, the FDA issued an FDA Form-483 identifying four
27 inspectional observations resulting from an FDA inspection that concluded on
February 10, 2023. The Company provided its response plan to the FDA on March
28 3, 2023, and has since completed the associated remediation workstreams to fully
address these observations.

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

7 The second observation asserts that the TabloCart with Prefiltration (the
8 "TabloCart"), requires prior 510(k) clearance for marketing authorization.
9 TabloCart, an accessory to the Tablo System, launched in the third quarter of 2022
10 and sales to date have not been material to the Company's financial results. The
11 Company intends to work collaboratively with the FDA to resolve this observation,
12 including potentially submitting a 510(k) on TabloCart.

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

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

22 61. On this news, Outset's stock price fell \$1.20, or 5.9%, to close at \$19.26 per share
23 on July 10, 2023.

24 62. On July 18, 2024, the FDA Warning Letter was published on the FDA's website.

25 The FDA Warning Letter stated:

26 **Unapproved Device Violations**

- 27 1. The TabloCart with Prefiltration is adulterated under section 501(f)(1)(B)
28 of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an
approved application for premarket approval (PMA) in effect pursuant to
section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application
for an investigational device exemption under section 520(g) of the Act,
21 U.S.C. § 360j(g). The device is also misbranded under section 502(o)
of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of
its intent to introduce the device into commercial distribution, as required
by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR
807.81(a)(3)(i).

You have not submitted any premarket notification to the Agency for the
TabloCart with Prefiltration. However, the evidence and marketing
materials reviewed at the inspection and found on your website
[www.outsetmedical.com] on March 15, 2023, indicate that the TabloCart
with Prefiltration is a device. For example, your materials state that the
TabloCart with Prefiltration is used for "prefiltration"; has "[t]hree
customizable filter configurations [to] enable added filtration of carbon and
sediment, depending on a facility's incoming water quality"; and is intended
to be used with your Tablo Hemodialysis System.

1 It appears that the TabloCart with Prefiltration could be classified under
2 21 CFR 876.5665 (Water purification system for hemodialysis), a Class II
3 device type subject to premarket notification:

4 “(a) Identification. A water purification system for hemodialysis is a device
5 that is intended for use with a hemodialysis system and that is intended to
6 remove organic and inorganic substances and microbial contaminants from
7 water used to dilute dialysate concentrate to form dialysate. This generic
8 type of device may include a water softener, sediment filter, carbon filter,
9 and water distillation system.”

10 TabloCart with Prefiltration appears to meet this definition because:

- 11 ○ It is intended to be used with a Hemodialysis System
- 12 ○ It is intended to remove organic and inorganic substances from
13 water used to dilute dialysate concentrate to form dialysate

14 The TabloCart with Prefiltration is intended to improve the incoming water
15 quality and lower the pressure specifications for the Tablo Hemodialysis
16 System to include water that exceeds (b)(4). Inadequate filtration of lower
17 quality incoming water may result in adverse effects arising from organic
18 and inorganic contaminants that might be found in improperly prepared
19 dialysis fluid. As noted above, your firm is marketing this device without
20 clearance or premarket approval.

21 For a device requiring premarket approval, the notification required by
22 section 510(k) is deemed satisfied when a PMA is pending before the FDA
23 [21 CFR 807.81(b)]. The kind of information that your firm needs to submit
24 in order to obtain approval or clearance for the devices is described on the
25 Internet at
26 <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>. The FDA will evaluate the information
27 that your firm submits and decide whether the product may be legally
28 marketed.

- 29 2. The Tablo Hemodialysis System is adulterated under section 501(f)(1)(B)
30 of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an
31 approved application for premarket approval (PMA) in effect pursuant to
32 section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application
33 for an investigational device exemption under section 520(g) of the Act,
34 21 U.S.C. § 360j(g). The device is also misbranded under section 502(o)
35 of the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of
36 its intent to introduce the device into commercial distribution, as required
37 by section 510(k) of the Act, 21 U.S.C. § 360(k), and 21 CFR
38 807.81(a)(3)(i).

39 You currently have clearance for the Tablo Hemodialysis System under
40 K223248 for the following indications:

41 “The Tablo Hemodialysis System is indicated for use in patients with acute
42 and/or chronic renal failure, with or without ultrafiltration, in an acute or
43 chronic care facility or in the home. Treatments must be administered under
44 a physician’s prescription and observed by a trained individual who is
45 considered competent in the use of the device. Treatment types available
46 include Intermittent Hemodialysis (IHD), Sustained Low Efficiency

1 Dialysis (SLED/ SLEDD), Prolonged Intermittent Renal Replacement
2 Therapy (PIRRT), and Isolated Ultrafiltration.”

3 However, the evidence reviewed at the inspection and marketing materials
4 found on your website [www.outsetmedical.com] on May 11, 2023, show
5 promotion of the Tablo Hemodialysis System for continuous renal
6 replacement therapy (CRRT) treatment. For example, materials on your
7 website state that two large hospitals converted to a program consisting
8 solely of the Tablo Hemodialysis System and state, “This major conversion
9 eliminated the need for several types of dialysis machines for different
10 clinical needs, including intermittent hemodialysis (IHD) in the dialysis unit
11 and continuous renal replacement therapy (CRRT) in critical care.” Other
12 materials on your website state that multiple hospitals who had established
13 CRRT treatment programs “converted those CRRT programs over to Tablo
14 with Extended Therapy” and states, “They also replaced their CRRT
15 machines with Tablo with XT...”

16 We evaluated the FDA databases and did not find documentation that you
17 have a cleared 510(k) or a premarket notification in-house for an Indications
18 for Use that includes CRRT treatment. In addition, we note that during
19 review of K223248, you confirmed that CRRT is distinct from the cleared
20 indications for use, device specifications, and treatment modalities for the
21 Tablo Hemodialysis System, and that PIRRT transitions to CRRT at (b)(4)
22 of use1. Patients who require CRRT are typically hospitalized with acute
23 illness resulting in acute kidney injury and possible severe hemodynamic
24 instability, and the devices that provide CRRT treatment have unique
25 features to enable continuous treatment (> 24 hours) for this patient
26 population. Systems that cannot safely and reliably perform CRRT raise
27 serious public health concerns when used for CRRT treatment, because
28 failure of dialysis systems performing CRRT may result in fluid and
electrolyte imbalances, inadequate ultrafiltration, infection, and patient
harm/death. This change represents a significant modification outside the
scope of the K223248 clearance that could significantly affect safety or
effectiveness, resulting in a new device such that a separate, additional
510(k) premarket notification must be submitted [see 21 CFR
807.81(a)(3)(i)]. Thus, the sale of the Tablo Hemodialysis System for
CRRT is unlawful.

63. On August 2, 2023, after the market closed, in connection with its second quarter
2023 financial results, Outset issued a press release announcing that it had paused the shipment
of TabloCart, pending the FDA’s 510(k) clearance. The Company also stated that it expected its
2023 revenue to be at the low end of its previously projected range as a result of the shipment
pause. Specifically, the Company stated, in relevant part:

The Company also announced it has paused the shipment of TabloCart with
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.

“Since receiving the Warning Letter on July 6, we have made the decision to file a
510(k) for TabloCart with Prefiltration and pause distribution of the product until a
510(k) clearance has been granted,” added Trigg. “As we look ahead to the second

1 half of the year, we expect our strong momentum both in the acute and home end
2 markets to continue to drive the business.”

3 * * *

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

9 64. On this news, Outset’s stock price fell \$1.97, or 10.2%, to close at \$17.39 per share
10 on August 3, 2023.

11 65. On August 3, 2023, the Company filed with the SEC its Form 10-Q for the period
12 ended June 30, 2023 (“Q2 2023 Form 10-Q”), affirming the previously reported financial results.

13 The report stated the following regarding the Company’s sales practices:

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

18 * * *

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

28 66. On October 12, 2023, after the market close, Outset issued a press release reporting
preliminary third quarter results. In the press release, the Company stated that preliminary
revenue for the third quarter was \$30.4 million, and Outset “now expects revenue for 2023 to be
approximately \$130 million.”

67. According to the Company, “Growth in the quarter was dampened by a larger-
than-expected impact in the field from the recent FDA warning letter, and early signs of a more
cautious outlook on capital spending that we see as a headwind continuing through the fourth
quarter.”

- 1 • Recorded net revenue of \$30.5 million in the fourth quarter, bringing 2023
2 revenue to \$130.4 million, a 13% increase compared to \$115.4 million in
3 2022.
- 4 • Increased gross margin in the fourth quarter by nearly 900 basis points from
5 the prior-year period. Fourth quarter gross margin reached 25.3% (26.7%
6 on a non-GAAP basis) compared to 16.5% (17.1% on a non-GAAP basis)
7 in the fourth quarter of 2022. Gross margin for the full year was 22.2%
8 (23.6% on a non-GAAP basis) compared to 15.5% (16.1% on a non-GAAP
9 basis) in 2022.

10 * * *

11 **Full Year 2024 Financial Guidance**

12 Outset reaffirmed its previously provided guidance for 2024, including revenue of
13 \$145 million to \$153 million, growing 12% to 18% over 2023, and non-GAAP
14 gross margin in the low-30% range for 2024, exiting the year in the mid-30% range
15 for the fourth quarter.

16 76. On February 21, 2024, the Company filed with the SEC its Form 10-K for the fye
17 December 31, 2023 (“2023 Form 10-K”), affirming the previously reported financial results. The
18 Company stated, in relevant part, as follows:

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

* * *

We primarily sell our solutions through our direct sales organization, which covers
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
and fleet expansion of Tablo at existing customer sites. In addition, our field
service 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.

* * *

1 If we fail to retain our sales and marketing personnel, fail to increase our sales and
2 marketing capabilities or develop broad awareness of Tablo in a cost-effective
manner, we may not be able to generate revenue growth.

3 We have limited experience marketing and selling Tablo. We currently rely on our
4 direct sales force to sell Tablo in the United States, and any failure to maintain,
5 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.

6 77. On May 6, 2024, the Company issued a press release announcing that the FDA
7 had granted 510(k) clearance to TabloCart, stating in relevant part that “Outset has resumed
8 distribution of TabloCart with prefiltration and has product available to ship to customers in the
9 United States.”

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

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

18 * * *

19 **Full Year 2024 Financial Guidance**

20 Outset reaffirmed its previously provided guidance for 2024 including revenue of
21 \$145 million to \$153 million, growing 12% to 18% over 2023, and non-GAAP
22 gross margin in the low-30% range for the full year 2024, exiting the year in the
mid-30% range for the fourth quarter.

23 79. On May 9, 2024, the Company filed with the SEC its Form 10-Q for the period
24 ended March 31, 2024 (“Q1 2024 Form 10-Q”), affirming the previously reported financial
25 results. The report stated, in relevant part, the following concerning the Company’s sales
26 practices:

27 Driving adoption of Tablo in the acute care setting has been our primary focus to
28 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. Our experience in the
acute care market has demonstrated Tablo’s clinical flexibility and operational

1 versatility, while also delivering meaningful cost savings to the providers. We plan
2 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.

3 * * *

4 We primarily sell our solutions through our direct sales organization, which covers
5 most major metropolitan markets in the United States. Our sales organization is
6 comprised of our capital sales team, responsible for generating new customer
7 demand for Tablo, and our clinical sales team, responsible for driving utilization
8 and fleet expansion of Tablo at existing customer sites. In addition, our field
9 service team provides maintenance services and product support to our customers.
Our field sales and service teams represent 49% of our total full-time employees as
of March 31, 2024. 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.

10 80. The above statements identified in ¶¶ 63, 65-68, 70-72, 74-79 were materially false
11 and/or misleading, and failed to disclose material adverse facts about the Company's business,
12 operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that Outset
13 lacked the sales team and process to execute on the ramp of Tablo sales; (2) that, as a result of the
14 foregoing, the Company's revenue growth would be adversely impacted; and (3) that, as a result
15 of the foregoing, Defendants' positive statements about the Company's business, operations, and
16 prospects were materially misleading and/or lacked a reasonable basis.

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

22 [N]ew console placements were below our expectations and will be lower than we
23 originally forecasted for the year. We are taking clear steps to improve our
24 execution and grow the business over the long term to bring the benefits of Tablo
to 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
second quarter of 2023, driven by a decline in product revenue to \$19.2 million.
28 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

1 gross profit was \$9.8 million, compared to \$7.7 million for the second quarter of
2 2023. Total gross margin was 35.7%, compared to 21.4% in the second quarter of
3 2023.

4 * * *

5 **Full Year 2024 Financial Guidance**

6 Outset now expects 2024 revenue to be approximately \$110 million, revised from
7 a prior range of \$145 million to \$153 million, and non-GAAP gross margin to be
8 in the low-to-mid 30% range, revised from prior guidance in the low-30% range for
9 2024 and exiting the year in the mid-30% range for the fourth quarter.

10 82. On that same date, the Company held its second quarter 2024 earnings conference
11 call announcing the Company's financial results for the quarter. During that earnings call,
12 Defendant Trigg disclosed the Company would have to undergo "sales team and process
13 restructuring" and would be unable to deliver on a ramp of TabloCart as previously forecast.
14 Specifically, during the earnings call, Defendant Trigg stated:

15 What we're experiencing is a temporary dislocation of converting the pipeline to
16 revenue on our timeline due to the changes in customer profile and process and the
17 improvements needed in our own sales execution.

18 * * *

19 Given the depth and breadth of the sales team and process restructuring, we expect
20 it to take several quarters to fully implement and realize the many benefits that will
21 come from it. As we look ahead to the second half of the year, we now know it
22 will not be possible to execute this transformation given the expected
23 accompanying disruption while simultaneously delivering on the ramp we
24 previously forecasted. As a result, we expect the second half of 2024 will look
25 similar to the first half with expected revenue for the year of approximately \$110
26 million.

27 83. On this news, the Company's share price fell \$2.33, or 68.53%, to close at \$1.07
28 per share on August 8, 2024.

29 **CLASS ACTION ALLEGATIONS**

30 84. Plaintiff brings this action as a class action pursuant to Rule 23(a) and (b)(3) of the
31 Federal Rules of Civil Procedure on behalf of themselves and a class, consisting of all persons
32 and entities who purchased or otherwise acquired Outset securities between September 15, 2020,
33 and August 7, 2024, inclusive, and who were damaged thereby (the "Class"). Excluded from the
34 Class are Defendants, the officers and directors of the Company, at all relevant times, members

1 of their immediate families and their legal representatives, heirs, successors, or assigns, and any
2 entity in which Defendants have or had a controlling interest.

3 85. The members of the Class are so numerous that joinder of all members is
4 impracticable. While the exact number of Class members is unknown to Plaintiff at this time and
5 can only be ascertained through appropriate discovery, Plaintiff believes that there are at least
6 hundreds or thousands of members in the proposed Class. Throughout the Class Period, Outset
7 common stock actively traded on NASDAQ (an open and efficient market) under the symbol
8 “OM.” Millions of Outset shares were traded publicly during the Class Period on the NASDAQ.

9 86. Record owners and other members of the Class may be identified from records
10 maintained by Outset or its transfer agent and may be notified of the pendency of this action by
11 mail, using a form of notice similar to that customarily used in securities class actions.

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

- 15 a. whether Defendants violated the Exchange Act by the acts and omissions
16 as alleged herein;
- 17 b. whether Defendants knew or recklessly disregarded that their statements
18 and/or omissions were false and misleading;
- 19 c. whether documents, press releases, and other statements disseminated to
20 the investing public and the Company’s shareholders during the Class
21 Period misrepresented material facts about the business, operations, and
22 prospects of Outset;
- 23 d. whether statements made by Defendants to the investing public during the
24 Class Period misrepresented and/or omitted to disclose material facts about
25 the business, operations, and prospects of Outset;
- 26 e. whether the market price of Outset securities during the Class Period was
27 artificially inflated due to the material misrepresentations and failures to
28 correct the material misrepresentations complained of herein; and

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

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

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

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

15 **UNDISCLOSED ADVERSE INFORMATION**

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

22 92. During the Class Period, Defendants materially misled the investing public,
23 thereby inflating the price of Outset's securities, by publicly issuing false and/or misleading
24 statements and/or omitting material facts necessary to make Defendants' statements, as set forth
25 herein, not false and/or misleading. The statements and omissions were materially false and/or
26 misleading because they failed to disclose material adverse information and/or misrepresented
27 the truth about Outset's business, operations, and prospects as alleged herein.
28

1 looking statements” when made, and there were no meaningful cautionary statements identifying
2 important factors that could cause actual results to differ materially from those in the purportedly
3 forward-looking statements.

4 98. Alternatively, to the extent that the statutory safe harbor is determined to apply to
5 any forward-looking statements pleaded herein, Defendants are liable for those false and/or
6 misleading forward-looking statements because at the time each of those forward-looking
7 statements was made, the speaker had actual knowledge that the forward-looking statement was
8 materially false or misleading, and/or the forward-looking statement was authorized or approved
9 by an executive officer of Outset who knew that the statement was false when made. In addition,
10 to the extent any of the statements set forth above were accurate when made, they became
11 inaccurate or misleading because of subsequent events, and Defendants failed to update those
12 statements which later became inaccurate.

13 **LOSS CAUSATION**

14 99. 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’s securities and operated as a fraud or deceit on the Class.
17 When Defendants’ prior misrepresentations, information alleged to have been concealed,
18 fraudulent conduct, and/or the effect thereof were disclosed to the market, the price of Outset’s
19 stock fell precipitously, as the prior artificial inflation came out of the price.

20 100. The economic loss, *i.e.*, damages, suffered by Plaintiff and other Class members
21 was a direct result of Defendants’ false and misleading statements and fraudulent scheme to
22 artificially inflate the Company’s securities and the subsequent significant decline in the value of
23 the Company’s securities when the true facts started to be revealed.

24 **APPLICABILITY OF PRESUMPTION OF RELIANCE** 25 **(FRAUD-ON-THE-MARKET DOCTRINE)**

26 101. The market for Outset stock was open, well-developed, and efficient at all relevant
27 times. As a result of the materially false and/or misleading statements and/or failures to disclose
28 particularized in this complaint, Outset securities traded at artificially inflated and/or maintained

1 prices during the Class Period. Plaintiff and other members of the Class purchased the Company's
2 securities relying upon the integrity of the market price of Outset securities and market
3 information relating to Outset and have been damaged thereby.

4 102. At all times relevant, the market for Outset securities was an efficient market for
5 the following reasons, among others:

- 6 a. Outset was listed and actively traded on NASDAQ, a highly efficient and
7 automated market;
- 8 b. The market price of Outset securities reacted promptly to the determination
9 of public information regarding the Company
- 10 c. As a regulated issuer, Outset filed periodic public reports with the SEC
11 and/or the NASDAQ during the Class Period;
- 12 d. Outset regularly communicated with public investors via established
13 market communication mechanisms, including through regular
14 dissemination of press releases on the national circuits of major newswire
15 services and through other wide-ranging public disclosures, such as
16 communications with the financial press and other similar reporting
17 services; and/or
- 18 e. Outset was followed by securities analysts employed by brokerage firms
19 who wrote reports about the Company, and these reports were distributed
20 to the sales force and certain customers of their respective brokerage firms.
21 Each of these reports was publicly available and entered the public
22 marketplace.

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

1 Exchange Act and Rule 10b-5 promulgated thereunder. All Defendants are sued either as primary
2 participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged
3 below.

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

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

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

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

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

27 113. By virtue of the foregoing, Outset and the Individual Defendants each violated
28 § 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

1 position as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of
2 the Exchange Act.

3 **PRAYER FOR RELIEF**

4 WHEREFORE, Plaintiff prays for judgment as follows:

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

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

10 (c) Awarding Plaintiff and the Class their pre-judgment and post-judgment interest,
11 as well as reasonable costs and expenses incurred in this action, including attorneys' fees and
12 expert fees; and

13 (d) Awarding such equitable/injunctive or other further relief as the Court may deem
14 just and proper.

15 **JURY DEMAND**

16 Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff hereby demand
17 trial by jury of all issues that may be so tried.

18 Dated:

Respectfully submitted,

19
20
21 By: _____
22
23
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28