

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

**FORM 8-K**

**CURRENT REPORT**

**Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

**Date of Report (Date of earliest event reported): June 13, 2022**

**Outset Medical, Inc.**

(Exact name of Registrant as Specified in Its Charter)

**Delaware**  
(State or Other Jurisdiction  
of Incorporation)

**001-39513**  
(Commission File Number)

**20-0514392**  
(IRS Employer  
Identification No.)

**3052 Orchard Dr.,  
San Jose, California**  
(Address of Principal Executive Offices)

**95134**  
(Zip Code)

**Registrant's Telephone Number, Including Area Code: (669) 231-8200**

**Not Applicable**  
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, \$0.001 par value per share	OM	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

## Item 2.02 Results of Operations and Financial Condition.

On June 13, 2022, Outset Medical, Inc. (the “**Company**”) issued a press release (the “**Press Release**”) announcing, among other items, guidance for second quarter 2022 revenue, that it expects to provide an update to its full year 2022 revenue and other financial goals during its next quarterly update in early August, and its suspension of prior guidance until then. A copy of the Press Release is attached hereto as Exhibit 99.1 and incorporated into this Item 2.02 by reference.

The information contained in this Item 2.02 and the portion of Exhibit 99.1 hereto regarding the Company’s guidance for second quarter 2022 revenue, plans to provide an update to its full year 2022 revenue and other financial goals and its suspension of prior guidance shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, (the “**Securities Act**”) or the Exchange Act, except as expressly set forth by specific reference in such a filing.

## Item 8.01. Other Events.

In the Press Release, the Company also announced that it has implemented a shipment hold on the distribution of its Tablo Hemodialysis System for home use pending the Food and Drug Administration’s (“**FDA**”) review and clearance of a 510(k) the Company submitted for changes made since the device’s original March 2020 clearance.

The Company has not identified any safety issues with Tablo. The Company will continue to market and ship Tablo for use by healthcare professionals in chronic and acute care settings. Devices that are already distributed to home users have not been removed and current users can continue to work with their healthcare providers on appropriate treatment.

## Forward-Looking Statements

This report and the exhibit attached hereto contain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on management’s current assumptions and expectations of future events and trends, which affect or may affect the Company’s business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements include, but are not limited to, statements about the Company’s possible or assumed future results of operations and financial position, including expectations regarding projected revenues, statements regarding the Company’s shipment hold of new Tablo Systems for home use including anticipated impacts thereof and potential timing for resuming such shipments, and statements regarding the Company’s anticipated regulatory review timeline and process. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release include the Company’s ability to obtain necessary clearances or approvals for its products on a timely basis or at all, as well as other factors which can be found in the Risk Factors section of the Company’s public filings with the Securities and Exchange Commission (“**SEC**”), including its Annual Report on Form 10-K for the fiscal year ended December 31, 2021 and subsequent quarterly reports filed with the SEC. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of their date and, except to the extent required by law, the Company undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise.

## Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release entitled “Outset Medical Announces Shipment Hold on New Tablo Systems for Home Use Pending FDA Review and Clearance of Recent 510(k) Submission” dated June 13, 2022</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

**Outset Medical, Inc.**

Date: June 13, 2022

By: \_\_\_\_\_  
/s/Nabeel Ahmed  
**Nabeel Ahmed**  
**Chief Financial Officer**

---

## **Outset Medical Announces Shipment Hold on New Tablo Systems for Home Use Pending FDA Review and Clearance of Recent 510(K) Submission**

### **Investor Webcast and Conference Call Scheduled for 5:00 p.m. EST**

**San Jose, CA – June 13, 2022** – Outset Medical, Inc. (Nasdaq: OM) (“Outset” or the “company”), today announced it has implemented a shipment hold on the distribution of its Tablo Hemodialysis System for home use pending the Food and Drug Administration’s (FDA) review and clearance of a 510(k) the company submitted for changes made since the device’s original March 2020 clearance.

Outset has not identified any safety issues with Tablo. The company will continue to market and ship Tablo for use by healthcare professionals in chronic and acute care settings. Devices that are already distributed to home users have not been removed and current users can continue to work with their healthcare providers on appropriate treatment.

As a result of the shipment hold, Outset now expects second quarter 2022 revenue of at least \$25 million. The company anticipates an update on the status of the regulatory review process in the third quarter and to provide an update to its 2022 revenue and other financial goals during its next quarterly update in early August. Until then, the company has suspended its prior guidance.

#### **Webcast and Conference Call Details**

Outset will host a conference call today at 2:00 p.m. PT/ 5:00 p.m. ET to discuss today’s updates. The dial-in numbers are (833) 614-1409 for domestic callers and (914) 987-7130 for international callers. The conference ID is 9710708. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at <https://investors.outsetmedical.com>. The webcast will be archived on the website following the completion of the call.

#### **Forward-Looking Statements**

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of historical fact are forward-looking statements. Forward-looking statements are based on management’s current assumptions and expectations of future events and trends, which affect or may affect the Company’s business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements include, but are not limited to, statements about the Company’s possible or assumed future results of operations and financial position, including expectations regarding projected revenues, statements regarding the Company’s shipment hold of new Tablo shipments for home use including anticipated impacts thereof and potential timing for resuming such shipments and statements regarding the Company’s anticipated regulatory review and approval timeline and process. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release include the Company’s ability to obtain necessary clearances or approvals for its products on a timely basis or at all, as well as other factors which can be found in the Risk Factors section of Outset’s public filings with the Securities and Exchange Commission, including Outset’s latest annual and quarterly reports. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of their date and, except to the extent required by law, the Company undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise.

#### **About Outset Medical, Inc.**

Outset is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime and anywhere. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels, with 2-way wireless data transmission and a proprietary data analytics platform powering a new holistic approach to dialysis care. Tablo is a registered trademark of Outset Medical, Inc.

---

**Investor Contact**

Jim Mazzola

858-342-8272

[jmazzola@outsetmedical.com](mailto:jmazzola@outsetmedical.com)

**Media Contact**

Nicole Shannon

[nshannon@outsetmedical.com](mailto:nshannon@outsetmedical.com)

---

