

**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): July 7, 2023

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 8.01 Other Events.

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

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

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

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

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

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

Forward-Looking Statements

This report and the exhibit attached hereto contain 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 plans to address the Warning Letter. 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 report and the exhibit attached hereto can be found in the Risk Factors section of the Company’s public filings with the Securities and Exchange Commission, including its 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit Number</u>	<u>Description</u>
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: July 7, 2023

By:

/s/ Nabeel Ahmed
Nabeel Ahmed
Chief Financial Officer