

**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): October 12, 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
<b>Common Stock, \$0.001 par value per share</b>	<b>OM</b>	<b>The Nasdaq Stock Market LLC</b>

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.

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**Item 2.02 Result of Operations and Financial Condition.**

On October 12, 2023, Outset Medical, Inc. (the “**Company**”) issued a press release announcing expected revenue and gross margin for the third quarter ended September 30, 2023, as well as updated financial guidance for 2023 revenue. A copy of the Company’s press release is furnished herewith as Exhibit 99.1.

Certain financial information contained in Exhibit 99.1 is preliminary, unaudited and subject to change or adjustment in connection with the completion of the Company’s quarter-end closing processes and the preparation of its unaudited financial statements for the third quarter ended September 30, 2023, which will be contained in the Company’s related Quarterly Report on Form 10-Q.

The information contained in this Item 2.02 and Exhibit 99.1 hereto 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**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 expected results of operations, including expected revenue and gross margin for the third quarter of 2023, statements about the Company’s possible or assumed future results of operations and financial position, including expectations regarding projected revenues for 2023, gross margin, operating expenses, capital expenditures, profitability and outlook; statements regarding the Company’s overall business strategy, plans and objectives of management; the Company’s expectations regarding the market sizes and growth potential for Tablo and the total addressable market opportunities for Tablo; continued execution of the Company’s initiatives designed to expand gross margins; the Company’s ability to respond to and resolve any reports, observations or other actions by the Food and Drug Administration or other regulators in a timely and effective manner; as well as the Company’s expectations regarding the impact of macroeconomic factors on the Company, its customers and suppliers. 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 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release entitled “Outset Medical Reports Preliminary Third Quarter 2023 Financial Results” dated October 12, 2023</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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: October 12, 2023

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

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**Outset Medical Reports Preliminary Third Quarter 2023 Financial Results*****Conference Call Scheduled for 4:30 p.m. ET***

**San Jose, CA – Oct. 12, 2023** – Outset Medical, Inc. (Nasdaq: OM) (“Outset” or the “Company”), today announced preliminary financial results for the third quarter ended Sept. 30, 2023, and provided updated financial guidance for 2023.

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

“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,” said Leslie Trigg, Chair and Chief Executive Officer. “Importantly, we did not see deals fall out of our pipeline and our economic value proposition remains resonant and differentiated. Our confidence around generating sustained long-term growth and reaching profitability remains high.”

**Webcast and Conference Call Details**

Outset will host a conference call today, Oct. 12, 2023, at 1:30 p.m. PT / 4:30 p.m. ET to discuss its preliminary third quarter 2023 results. Those interested in listening to the conference call may do so by registering online. Once registered, participants will receive dial-in numbers and a unique pin to join the call. Participants are encouraged to register more than 15 minutes before the start of the call. 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.

**Use of Non-GAAP Financial Measures**

The Company may report non-GAAP results for gross profit/loss, gross margin, operating expenses, operating margins, net income/loss, basic and diluted net income/loss per share, other income/loss, and cash flows. These non-GAAP financial measures are in addition to, and not a substitute for, or superior to, financial measures calculated in accordance with GAAP. The Company’s financial measures under GAAP include stock-based compensation expense, as listed in the itemized reconciliations between GAAP and non-GAAP financial measures included in this press release. Management has excluded the effects of this non-cash expense item in non-GAAP measures to assist investors in analyzing and assessing past and future operating performance and period-to-period comparisons. There are limitations related to the use of non-GAAP financial measures because they are not prepared in accordance with GAAP, may exclude significant expenses required by GAAP to be recognized in the Company’s financial statements, and may not be comparable to non-GAAP financial measures used by other companies. The Company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the Appendix A of this press release.

**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 expected results of operations, including expected revenue and gross margin for the third quarter of 2023, statements about the Company’s possible or assumed future results of operations and financial position, including expectations regarding projected revenues for 2023, gross margin, operating expenses, capital expenditures, profitability and outlook; statements regarding the Company’s overall business strategy, plans and objectives of management; the

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Company's expectations regarding the market sizes and growth potential for Tablo and the total addressable market opportunities for Tablo; continued execution of the Company's initiatives designed to expand gross margins; the Company's ability to respond to and resolve any reports, observations or other actions by the Food and Drug Administration or other regulators in a timely and effective manner; as well as the Company's expectations regarding the impact of macroeconomic factors on the Company, its customers and suppliers. 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 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.

The financial information contained in this press release is preliminary, unaudited and subject to change or adjustment in connection with the completion of the Company's quarter-end closing process and the preparation of its unaudited financial statements for the third quarter ended Sept. 30, 2023, which will be contained in the Company's related Quarterly Report on Form 10-Q.

#### **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. The Tablo® Hemodialysis System, FDA cleared for use from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. 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**

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#### **Media Contact**

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**Outset Medical, Inc.**  
**Gross Margin – Non-GAAP**  
(unaudited)

**Reconciliation between preliminary GAAP and non-GAAP gross margin:**

	Three Months Ended		September 30,		Nine Months Ended		September 30,	
	2023		2022		2023		2022	
	2023	2022	2023	2022	2023	2022	2023	2022
<b>Preliminary GAAP gross margin</b>	23.6	15.6	21.5	15.1	%	%	%	%
Preliminary stock-based compensation expense	2.0	0.8	1.4	0.6				
<b>Preliminary non-GAAP gross margin</b>	<u>25.6</u>	<u>16.4</u>	<u>22.9</u>	<u>15.7</u>	%	%	%	%

