

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): August 7, 2024

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 Result of Operations and Financial Condition.

On August 7, 2024, Outset Medical, Inc. (the “Company”) issued a press release and will hold its second quarter 2024 earnings conference call announcing the Company’s financial results for the quarter ended June 30, 2024, as well as updated financial guidance for 2024 revenue and non-GAAP gross margin. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

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 (the “Securities Act”), 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 possible or assumed future results of operations and financial position, including expectations regarding projected revenues, gross margin, operating expenses, capital expenditures, cash burn, cash position, profitability and outlook; statements regarding the anticipated impacts and benefits of the Company’s cost reduction actions, initiatives to optimize the commercial organization and restructurings; 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 Second Quarter 2024 Financial Results” dated August 7, 2024</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)



## Outset Medical Reports Second Quarter 2024 Financial Results

**San Jose, CA – August 7, 2024** – Outset Medical, Inc. (Nasdaq: OM) (“Outset” or the “Company”), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis, today reported financial results for the second quarter ended June 30, 2024.

“During the quarter, the number of treatments performed each month on Tablo continued at record levels, as utilization remained high and gross margin materially expanded as it has each quarter for more than 3 years,” said Leslie Trigg, Chair and Chief Executive Officer. “These results reflect the strength and differentiation of Tablo and the positive impact it is having on the lives of patients and providers.

“At the same time, new console placements were below our expectations and will be lower than we originally forecasted for the year. We are taking clear steps to improve our execution and grow the business over the long term to bring the benefits of Tablo to even more providers and dialysis patients.”

### Second Quarter 2024 Financial Results

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. Service and other revenue was \$8.2 million, an increase of 21.5% compared to \$6.7 million in the second quarter of 2023. Recurring revenue from the sale of Tablo cartridges and service increased by 24% as compared to the prior-year period.

Total gross profit was \$9.8 million, compared to \$7.7 million for the second quarter of 2023. Total gross margin was 35.7%, compared to 21.4% in the second quarter of 2023. On a non-GAAP basis, gross margin improved to 37.3% from 22.5% in the second quarter of 2023. Product gross profit was \$8.7 million, compared to \$7.1 million in the second quarter of 2023. Product gross margin was 45.1%, compared to 24.3% in the second quarter of 2023. Service and other gross profit was \$1.1 million, compared to \$0.6 million in the second quarter of 2023. Service and other gross margin was 13.6%, compared to 8.7% in the second quarter of 2023.

Operating expenses declined 21% from the prior-year period to \$40.5 million, including research and development (R&D) expenses of \$9.7 million, sales and marketing (S&M) expenses of \$18.1 million, and general and administrative (G&A) expenses of \$12.7 million. This compared to operating expenses of \$51.2 million in the second quarter of 2023, including R&D expenses of \$14.9 million, S&M expenses of \$25.0 million, and G&A expenses of \$11.3 million.

Excluding stock-based compensation expense and severance and related charges, net of adjustments to compensation accrual, non-GAAP operating expenses were \$31.2 million, including R&D expenses of \$7.5 million, S&M expenses of \$15.5 million, and G&A expenses of \$8.2 million.

Net loss was \$34.5 million, or \$(0.66) per share, compared to net loss of \$44.0 million, or \$(0.90) per share, for the same period in 2023. On a non-GAAP basis, net loss was \$24.7 million, or \$(0.47) per share, compared to non-GAAP net loss of \$33.9 million, or \$(0.69) per share for the same period in 2023.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$198.2 million as of June 30, 2024.

### Full Year 2024 Financial Guidance

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

### Webcast and Conference Call Details

Outset will host a conference call today, August 7, 2024, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its second quarter 2024 financial 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.

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## **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. As listed in the itemized reconciliations between GAAP and non-GAAP financial measures included in this press release, the Company's GAAP financial measures include stock-based compensation expense, as well as severance and related charges net of the reversal of compensation accruals for impacted employees. Stock-based compensation is a non-cash expense, and severance and related charges arise outside the ordinary course of continuing operations and are not reflective of the Company's current operating performance. As such, management has excluded the effects of these items 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 possible or assumed future results of operations and financial position, including expectations regarding projected revenues, gross margin, operating expenses, capital expenditures, cash burn, cash position, profitability and outlook; statements regarding the anticipated impacts and benefits of the Company's cost reduction actions, initiatives to optimize the commercial organization and restructurings; 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.

## **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**

Jim Mazzola

Investor Relations

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**Outset Medical, Inc.**  
**Condensed Statements of Operations**  
*(in thousands, except per share amounts)*  
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
<b>Revenue:</b>				
Product revenue	\$ 19,238	\$ 29,330	\$ 39,666	\$ 57,109
Service and other revenue	8,150	6,710	15,890	12,398
Total revenue	27,388	36,040	55,556	69,507
<b>Cost of revenue:</b>				
Cost of product revenue <sup>(2)</sup>	10,567	22,212	23,148	43,029
Cost of service and other revenue	7,039	6,125	14,411	12,347
Total cost of revenue	17,606	28,337	37,559	55,376
Gross profit <sup>(1)</sup>	9,782	7,703	17,997	14,131
Gross margin <sup>(1)</sup>	35.7 %	21.4 %	32.4 %	20.3 %
<b>Operating expenses:</b>				
Research and development <sup>(2)</sup>	9,734	14,906	22,369	28,699
Sales and marketing <sup>(2)</sup>	18,128	24,985	39,176	49,318
General and administrative <sup>(2)</sup>	12,684	11,290	24,128	23,077
Total operating expenses	40,546	51,181	85,673	101,094
Loss from operations	(30,764)	(43,478)	(67,676)	(86,963)
Interest income and other income, net	2,471	2,668	5,569	5,316
Interest expense	(6,010)	(3,103)	(11,978)	(6,045)
Loss before provision for income taxes	(34,303)	(43,913)	(74,085)	(89,059)
Provision for income taxes	151	133	313	325
Net loss	\$ (34,454)	\$ (44,046)	\$ (74,398)	\$ (89,384)
Net loss per share, basic and diluted	\$ (0.66)	\$ (0.90)	\$ (1.45)	\$ (1.79)
Shares used in computing net loss per share, basic and diluted	51,880	48,951	51,391	49,085

(1) Gross profit and gross margin by source consisted of the following:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
<b>Gross profit</b>				
Product revenue	\$ 8,671	\$ 7,118	\$ 16,518	\$ 14,080
Service and other revenue	1,111	585	1,479	51
Total gross profit	\$ 9,782	\$ 7,703	\$ 17,997	\$ 14,131
<b>Gross margin</b>				
Product revenue	45.1 %	24.3 %	41.6 %	24.7 %
Service and other revenue	13.6 %	8.7 %	9.3 %	0.4 %
Total gross margin	35.7 %	21.4 %	32.4 %	20.3 %

(2) Include stock-based compensation expense and severance and related charges, net as follows:

<u>Stock-based compensation expense</u>	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Cost of revenue	\$ 531	\$ 403	\$ 796	\$ 761
Research and development	2,293	2,824	4,625	5,439
Sales and marketing	2,494	3,545	3,953	6,143
General and administrative	4,502	3,333	8,649	6,300
Total stock-based compensation expense	\$ 9,820	\$ 10,105	\$ 18,023	\$ 18,643

<u>Severance and related charges, net*</u>	Three Months Ended June 30,		Six Months Ended June 30,	
	2024†	2023	2024	2023
Cost of revenue	\$ (78)	\$ —	\$ 201	\$ —
Research and development	(29)	—	963	—
Sales and marketing	99	—	892	—
General and administrative	(41)	—	370	—
Total severance and related charges, net	\$ (49)	\$ —	\$ 2,426	\$ —

\* Net of adjustments to compensation accrual

† These amounts represent the change in estimated accrual from March 31, 2024

**Outset Medical, Inc.**  
**Condensed Balance Sheets**  
*(in thousands, except per share amounts)*

	June 30, 2024 (Unaudited)	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 37,859	\$ 68,509
Short-term investments	156,989	134,815
Accounts receivable, net	34,121	32,980
Inventories	61,599	49,215
Prepaid expenses and other current assets	4,569	5,700
Total current assets	295,137	291,219
Restricted cash	3,329	3,329
Property and equipment, net	10,873	13,273
Operating lease right-of-use assets	4,675	5,375
Other assets	520	605
Total assets	\$ 314,534	\$ 313,801
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 5,255	\$ 5,827
Accrued compensation and related benefits	11,431	19,005
Accrued expenses and other current liabilities	9,747	13,459
Accrued warranty liability	2,199	3,712
Deferred revenue, current	13,108	11,727
Operating lease liabilities, current	1,693	1,593
Total current liabilities	43,433	55,323
Accrued interest	1,762	896
Deferred revenue	130	101
Operating lease liabilities	3,616	4,482
Term loans	196,994	130,113
Total liabilities	245,935	190,915
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of June 30, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of June 30, 2024 and December 31, 2023; 52,084 and 50,317 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	52	50
Additional paid-in capital	1,104,994	1,084,515
Accumulated other comprehensive income (loss)	(302)	68
Accumulated deficit	(1,036,145)	(961,747)
Total stockholders' equity	68,599	122,886
Total liabilities and stockholders' equity	\$ 314,534	\$ 313,801

**Outset Medical, Inc.**  
**Condensed Statements of Cash Flows**  
*(in thousands)*  
(unaudited)

	<b>Six Months Ended June 30,</b>	
	<b>2024</b>	<b>2023</b>
Net cash used in operating activities	\$ (79,247)	\$ (72,932)
Net cash (used in) provided by investing activities	(20,090)	29,796
Net cash provided by financing activities	68,687	6,320
Net decrease in cash, cash equivalents and restricted cash	(30,650)	(36,816)
Cash, cash equivalents and restricted cash at beginning of the period	71,838	76,533
Cash, cash equivalents and restricted cash at end of the period <sup>(1)</sup>	\$ 41,188	\$ 39,717

<sup>(1)</sup> The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the accompanying condensed balance sheets that sum to the total of the amounts shown in the accompanying condensed statements of cash flows (in thousands):

	<b>June 30,</b>	
	<b>2024</b>	<b>2023</b>
Cash and cash equivalents	\$ 37,859	\$ 36,388
Restricted cash	3,329	3,329
Total cash, cash equivalents and restricted cash*	\$ 41,188	\$ 39,717

\* The total cash, including restricted cash, cash equivalents and investment securities as of June 30, 2024 was \$198.2 million; compared to \$226.1 million as of June 30, 2023.



