

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): May 8, 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 May 8, 2024, Outset Medical, Inc. (the “Company”) issued a press release and will hold its first quarter 2024 earnings conference call announcing the Company’s financial results for the quarter ended March 31, 2024. 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, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

Jean-Olivier Racine will depart from his role as the Company's Chief Technology Officer, effective May 17, 2024, in connection with the workforce reduction plan described in Item 8.01 below.

In connection with his departure, and subject to his execution and non-revocation of a general release of claims in favor of the Company, Mr. Racine will receive severance benefits of (i) a lump sum payment equal to nine months of base salary and (ii) payment of premiums for COBRA continuation coverage for nine months, pursuant to the terms of the existing Change in Control and Severance Agreement between Mr. Racine and the Company most recently amended and restated effective February 7, 2024 (the “Severance Agreement”). The foregoing description is qualified by reference to the full text of the Severance Agreement, a form of which was filed as Exhibit 10.12 to the Company's Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission on February 21, 2024. In addition, the Compensation Committee of the Company’s Board of Directors approved accelerated vesting of 33,923 shares underlying Mr. Racine’s remaining unvested restricted stock units previously granted in June 2021, January 2022 and January 2023, which will become fully vested as of May 10, 2024.

**Item 8.01 Other Events.**

In May 2024, the Company implemented a workforce reduction plan to improve operational efficiencies, reduce operating expenses and streamline its overall organizational structure. As a result, the Company estimated and recognized restructuring charges of \$3.0 million in the first quarter of 2024 for employee severance and other termination benefits.

**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 First Quarter 2024 Financial Results” dated May 8, 2024</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: May 8, 2024

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

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## Outset Medical Reports First Quarter 2024 Financial Results

**San Jose, CA – May 8, 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 first quarter ended March 31, 2024.

“With our recent 510(k) clearance for TabloCart with Prefiltration, 12<sup>th</sup> consecutive quarter of gross margin expansion and strong sales pipeline growth during the quarter, we are well positioned to capitalize on the \$11 billion U.S. dialysis market 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.

“We also took cost-reduction steps during the quarter to help ensure we reach our profitability goals without the need for additional capital. We believe these actions, combined with continued gross margin expansion and a strong recurring revenue foundation, now provide us a clear path to achieve cash-flow breakeven sooner than previously expected.”

### First Quarter 2024 Financial Results

Revenue for the first quarter of 2024 was \$28.2 million compared to \$33.5 million in the first quarter of 2023, driven by an expected decline in product revenue to \$20.4 million. Service and other revenue was \$7.7 million, an increase of 36.1% compared to \$5.7 million in the first 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 \$8.2 million, compared to \$6.4 million for the first quarter of 2023. Total gross margin was 29.2%, compared to 19.2% in the first quarter of 2023. On a non-GAAP basis, gross margin improved to 31.1% from 20.3% in the first quarter of 2023. Product gross profit was \$7.8 million, compared to \$7.0 million of product gross profit in the first quarter of 2023. Product gross margin was 38.4%, compared to 25.1% in the first quarter of 2023. Service and other gross profit was \$0.4 million, compared to \$(0.5) million of service and other gross profit in the first quarter of 2023. Service and other gross margin was 4.8%, compared to (9.4)% in the first quarter of 2023.

Operating expenses declined 10% from the prior-year period to \$45.1 million, including research and development (R&D) expenses of \$12.6 million, sales and marketing (S&M) expenses of \$21.0 million, and general and administrative (G&A) expenses of \$11.4 million. This compared to operating expenses of \$49.9 million in the first quarter of 2023, including R&D expenses of \$13.8 million, S&M expenses of \$24.3 million, and G&A expenses of \$11.8 million.

Excluding stock-based compensation expense and severance and related charges, net of adjustments to compensation accrual, non-GAAP operating expenses were \$35.0 million, including R&D expenses of \$9.3 million, S&M expenses of \$18.8 million, and G&A expenses of \$6.9 million.

Net loss was \$(39.9) million, or \$(0.78) 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 \$(29.3) million, or \$(0.57) per share, compared to non-GAAP net loss of \$(35.4) million, or \$(0.72) per share for the same period in 2023.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$230.2 million as of March 31, 2024.

### Full Year 2024 Financial Guidance

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

### Webcast and Conference Call Details

Outset will host a conference call today, May 8, 2024, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its first 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 about the Company's ability to meet its profitability goals without the need for additional capital and expectations on the timing of achieving cash-flow breakeven; statements regarding the anticipated impacts and benefits of the Company's cost reduction actions; 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)

	<b>Three Months Ended</b>	
	<b>March 31,</b>	
	<b>2024</b>	<b>2023</b>
<b>Revenue:</b>		
Product revenue	\$ 20,428	\$ 27,779
Service and other revenue	7,740	5,688
<b>Total revenue</b>	<b>28,168</b>	<b>33,467</b>
<b>Cost of revenue:</b>		
Cost of product revenue <sup>(2)</sup>	12,581	20,817
Cost of service and other revenue	7,372	6,222
<b>Total cost of revenue</b>	<b>19,953</b>	<b>27,039</b>
<b>Gross profit</b> <sup>(1)</sup>	<b>8,215</b>	<b>6,428</b>
<b>Gross margin</b> <sup>(1)</sup>	<b>29.2 %</b>	<b>19.2 %</b>
<b>Operating expenses:</b>		
Research and development <sup>(2)</sup>	12,635	13,793
Sales and marketing <sup>(2)</sup>	21,048	24,333
General and administrative <sup>(2)</sup>	11,444	11,787
<b>Total operating expenses</b>	<b>45,127</b>	<b>49,913</b>
Loss from operations	(36,912)	(43,485)
Interest income and other income, net	3,098	2,648
Interest expense	(5,968)	(2,942)
Loss before provision for income taxes	(39,782)	(43,779)
Provision for income taxes	162	192
<b>Net loss</b>	<b>\$ (39,944)</b>	<b>\$ (43,971)</b>
Net loss per share, basic and diluted	\$ (0.78)	\$ (0.90)
Shares used in computing net loss per share, basic and diluted	50,901	48,783

<sup>(1)</sup> Gross profit and gross margin by source consisted of the following:

	Three Months Ended March 31,	
	2024	2023
<b>Gross profit</b>		
Product revenue	\$ 7,847	\$ 6,962
Service and other revenue	368	(534)
Total gross profit	\$ 8,215	\$ 6,428
<b>Gross margin</b>		
Product revenue	38.4 %	25.1 %
Service and other revenue	4.8 %	(9.4) %
Total gross margin	29.2 %	19.2 %

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

<u>Stock-based compensation expense</u>	Three Months Ended March 31,	
	2024	2023
Cost of revenue	\$ 265	\$ 358
Research and development	2,332	2,615
Sales and marketing	1,459	2,598
General and administrative	4,147	2,967
Total stock-based compensation expense	\$ 8,203	\$ 8,538

<u>Severance and related charges, net*</u>	Three Months Ended March 31,	
	2024	2023
Cost of revenue	\$ 279	\$ —
Research and development	990	—
Sales and marketing	793	—
General and administrative	411	—
Total severance and related charges, net	\$ 2,473	\$ —

\* Net of adjustments to compensation accrual



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

	March 31, 2024 <u>(Unaudited)</u>	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 32,176	\$ 68,509
Short-term investments	194,743	134,815
Accounts receivable, net	36,478	32,980
Inventories	55,839	49,215
Prepaid expenses and other current assets	6,155	5,700
Total current assets	325,391	291,219
Restricted cash	3,329	3,329
Property and equipment, net	11,953	13,273
Operating lease right-of-use assets	5,029	5,375
Other assets	540	605
Total assets	<u>\$ 346,242</u>	<u>\$ 313,801</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 6,773	\$ 5,827
Accrued compensation and related benefits	14,248	19,005
Accrued expenses and other current liabilities	11,968	13,459
Accrued warranty liability	3,200	3,712
Deferred revenue, current	12,839	11,727
Operating lease liabilities, current	1,642	1,593
Total current liabilities	50,670	55,323
Accrued interest	1,319	896
Deferred revenue	186	101
Operating lease liabilities	4,054	4,482
Term loans	196,813	130,113
Total liabilities	<u>253,042</u>	<u>190,915</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of March 31, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of March 31, 2024 and December 31, 2023; 51,702 and 50,317 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	52	50
Additional paid-in capital	1,095,097	1,084,515
Accumulated other comprehensive income (loss)	(258)	68
Accumulated deficit	(1,001,691)	(961,747)
Total stockholders' equity	<u>93,200</u>	<u>122,886</u>
Total liabilities and stockholders' equity	<u>\$ 346,242</u>	<u>\$ 313,801</u>

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

	<b>Three Months Ended March 31,</b>	
	<b>2024</b>	<b>2023</b>
Net cash used in operating activities	\$ (45,912)	\$ (44,756)
Net cash (used in) provided by investing activities	(59,031)	2,643
Net cash provided by financing activities	68,610	5,277
Net decrease in cash, cash equivalents and restricted cash	(36,333)	(36,836)
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>	\$ 35,505	\$ 39,697

<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>March 31,</b>	
	<b>2024</b>	<b>2023</b>
Cash and cash equivalents	\$ 32,176	\$ 36,386
Restricted cash	3,329	3,311
Total cash, cash equivalents and restricted cash*	\$ 35,505	\$ 39,697

\* The total cash, including restricted cash, cash equivalents and investment securities as of March 31, 2024 was \$230.2 million; compared to \$252.5 million as of March 31, 2023.

**Outset Medical, Inc.**  
**Results of Operations – Non-GAAP**  
*(in thousands, except per share amounts)*  
(unaudited)

**Reconciliation between GAAP and non-GAAP net loss per share:**

	Three Months Ended March 31,	
	2024	2023
GAAP net loss per share, diluted	\$ (0.78)	\$ (0.90)
Stock-based compensation expense	0.16	0.18
Severance and related charges, net	0.05	—
Non-GAAP net loss per share, diluted	<u>\$ (0.57)</u>	<u>\$ (0.72)</u>

**Reconciliation between GAAP and non-GAAP net loss:**

	Three Months Ended March 31,	
	2024	2023
GAAP net loss, diluted	\$ (39,944)	\$ (43,971)
Stock-based compensation expense	8,203	8,538
Severance and related charges, net	2,473	—
Non-GAAP net loss, diluted	<u>\$ (29,268)</u>	<u>\$ (35,433)</u>

**Reconciliation between GAAP and non-GAAP results of operations:**

	Three Months Ended March 31,	
	2024	2023
<b>GAAP gross profit</b>	<u>\$ 8,215</u>	<u>\$ 6,428</u>
Stock-based compensation expense	265	358
Severance and related charges, net	279	—
Non-GAAP gross profit	<u>\$ 8,759</u>	<u>\$ 6,786</u>
<b>GAAP gross margin</b>	29.2 %	19.2 %
Stock-based compensation expense	0.9	1.1
Severance and related charges, net	1.0	—
Non-GAAP gross margin	<u>31.1 %</u>	<u>20.3 %</u>
<b>GAAP research and development expense</b>	<u>\$ 12,635</u>	<u>\$ 13,793</u>
Stock-based compensation expense	(2,332)	(2,615)
Severance and related charges, net	(990)	—
Non-GAAP research and development expense	<u>\$ 9,313</u>	<u>\$ 11,178</u>
<b>GAAP sales and marketing expense</b>	<u>\$ 21,048</u>	<u>\$ 24,333</u>
Stock-based compensation expense	(1,459)	(2,598)
Severance and related charges, net	(793)	—
Non-GAAP sales and marketing expense	<u>\$ 18,796</u>	<u>\$ 21,735</u>
<b>GAAP general and administrative expense</b>	<u>\$ 11,444</u>	<u>\$ 11,787</u>
Stock-based compensation expense	(4,147)	(2,967)
Severance and related charges, net	(411)	—
Non-GAAP general and administrative expense	<u>\$ 6,886</u>	<u>\$ 8,820</u>
<b>GAAP total operating expense</b>	<u>\$ 45,127</u>	<u>\$ 49,913</u>
Stock-based compensation expense	(7,938)	(8,180)
Severance and related charges, net	(2,194)	—
Non-GAAP total operating expense	<u>\$ 34,995</u>	<u>\$ 41,733</u>

