

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): November 6, 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 November 6, 2024, Outset Medical, Inc. (the “Company”) issued a press release and will hold its third quarter 2024 earnings conference call announcing the Company’s financial results for the quarter ended September 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.

Exhibit Number	Description
99.1	Press Release entitled “Outset Medical Reports Third Quarter 2024 Financial Results” dated November 6, 2024
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: November 6, 2024

By: _____ /s/Nabeel Ahmed
Nabeel Ahmed
Chief Financial Officer

Outset Medical Reports Third Quarter 2024 Financial Results

San Jose, CA – November 6, 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 third quarter ended September 30, 2024.

“During the quarter, we made significant progress, achieving sequential revenue growth, expanding the Tablo footprint in both the acute and home care settings, boosting gross margin compared to last year and reaching a record level of recurring revenue,” said Leslie Trigg, Chair and Chief Executive Officer. “Meanwhile, we continued implementing our sales transformation, which is showing promising early results and is poised to significantly enhance our growth with acute-care providers.”

Third Quarter 2024 Financial Results

Revenue for the third quarter of \$28.7 million increased 5% compared to \$27.4 million in the second quarter and declined 6% from \$30.4 million in the third quarter of 2023. Product revenue of \$20.3 million rose 6% from \$19.2 million in the second quarter and declined 14% from \$23.5 million in the third quarter of 2023. Service and other revenue was \$8.4 million, roughly even with \$8.2 million in the second quarter and an increase of 22% compared to \$6.8 million in the third quarter of 2023. Recurring revenue from the sale of Tablo cartridges and service reached \$21 million, an increase of 4% from the second quarter and 17% as compared to the prior-year period.

Total gross profit of \$9.8 million was even with the second quarter and up 37% from \$7.2 million for the third quarter of 2023. Total gross margin of 34.3% declined 1.4 percentage points from 35.7% in the second quarter and rose nearly 11 percentage points compared to 23.6% in the third quarter of 2023. On a non-GAAP basis, gross margin of 36.4% declined less than 1 percentage point from 37.3% in the second quarter and rose nearly 11 percentage points from 25.6% in the third quarter of 2023. Product gross profit of \$8.8 million increased 1% from \$8.7 million in the second quarter and 31% compared to \$6.7 million in the third quarter of 2023. Product gross margin of 43.2% declined 1.9 percentage points from 45.1% in the second quarter and increased nearly 15 percentage points from 28.4% in the third quarter of 2023. Service and other gross profit of \$1.0 million was roughly even with the second quarter and doubled from \$0.5 million in the third quarter of 2023. Service and other gross margin of 12.5% declined 1.1 percentage points compared to 13.6% in the second quarter and increased 5.7 percentage points from 6.8% in the third quarter of 2023.

Operating expenses of \$33.7 million declined nearly 17% from the second quarter and 36% from the prior-year period. Research and development (R&D) expenses were \$8.1 million, sales and marketing (S&M) expenses were \$15.4 million, and general and administrative (G&A) expenses were \$10.1 million. This compared to operating expenses of \$52.6 million in the third quarter of 2023, including R&D expenses of \$16.1 million, S&M expenses of \$24.7 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 \$26.5 million, including R&D expenses of \$6.6 million, S&M expenses of \$13.6 million, and G&A expenses of \$6.3 million.

Net loss was \$27.9 million, or \$(0.55) per share, compared to net loss of \$46.2 million, or \$(0.93) per share, for the same period in 2023. On a non-GAAP basis, net loss was \$20.2 million, or \$(0.39) per share, compared to non-GAAP net loss of \$35.3 million, or \$(0.71) per share for the same period in 2023.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$179.0 million as of September 30, 2024.

Full Year 2024 Financial Guidance

Outset increased 2024 revenue guidance to approximately \$112 million from prior guidance of approximately \$110 million, and non-GAAP gross margin guidance to the mid-30% range from the low-to-mid 30% range.

Webcast and Conference Call Details

Outset will host a conference call today, November 6, 2024, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its third 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.

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
jmazzola@outsetmedical.com

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	\$ 20,305	\$ 23,531	\$ 59,971	\$ 80,640
Service and other revenue	8,361	6,831	24,251	19,229
Total revenue	<u>28,666</u>	<u>30,362</u>	<u>84,222</u>	<u>99,869</u>
Cost of revenue:				
Cost of product revenue ⁽²⁾	11,532	16,837	34,680	59,866
Cost of service and other revenue	7,314	6,368	21,725	18,715
Total cost of revenue	<u>18,846</u>	<u>23,205</u>	<u>56,405</u>	<u>78,581</u>
Gross profit ⁽¹⁾	9,820	7,157	27,817	21,288
Gross margin ⁽¹⁾	34.3 %	23.6 %	33.0 %	21.3 %
Operating expenses:				
Research and development ⁽²⁾	8,139	16,076	30,508	44,775
Sales and marketing ⁽²⁾	15,417	24,720	54,593	74,038
General and administrative ⁽²⁾	10,103	11,815	34,231	34,892
Total operating expenses	<u>33,659</u>	<u>52,611</u>	<u>119,332</u>	<u>153,705</u>
Loss from operations	(23,839)	(45,454)	(91,515)	(132,417)
Interest income and other income, net	2,149	2,573	7,718	7,889
Interest expense	(6,068)	(3,213)	(18,046)	(9,258)
Loss before provision for income taxes	<u>(27,758)</u>	<u>(46,094)</u>	<u>(101,843)</u>	<u>(133,786)</u>
Provision for income taxes	182	86	495	411
Net loss	<u>\$ (27,940)</u>	<u>\$ (46,180)</u>	<u>\$ (102,338)</u>	<u>\$ (134,197)</u>
Net loss per share, basic and diluted	<u>\$ (0.55)</u>	<u>\$ (0.93)</u>	<u>\$ (1.98)</u>	<u>\$ (2.72)</u>
Shares used in computing net loss per share, basic and diluted	<u>50,501</u>	<u>49,913</u>	<u>51,685</u>	<u>49,364</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Gross profit				
Product revenue	\$ 8,773	\$ 6,694	\$ 25,291	\$ 20,774
Service and other revenue	1,047	463	2,526	514
Total gross profit	\$ 9,820	\$ 7,157	\$ 27,817	\$ 21,288
Gross margin				
Product revenue	43.2 %	28.4 %	42.2 %	25.8 %
Service and other revenue	12.5 %	6.8 %	10.4 %	2.7 %
Total gross margin	34.3 %	23.6 %	33.0 %	21.3 %

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

<u>Stock-based compensation expense</u>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of revenue	\$ 296	\$ 620	\$ 1,092	\$ 1,381
Research and development	1,400	2,793	6,025	8,232
Sales and marketing	945	3,765	4,898	9,908
General and administrative	3,747	3,715	12,396	10,015
Total stock-based compensation expense	\$ 6,388	\$ 10,893	\$ 24,411	\$ 29,536

<u>Severance and related charges, net*</u>	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Cost of revenue	\$ 317	\$ —	\$ 518	\$ —
Research and development	161	—	1,124	—
Sales and marketing	873	—	1,765	—
General and administrative	20	—	390	—
Total severance and related charges, net	\$ 1,371	\$ —	\$ 3,797	\$ —

* Net of adjustments to compensation accrual

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

	September 30, 2024 <u>(Unaudited)</u>	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 33,287	\$ 68,509
Short-term investments	142,346	134,815
Accounts receivable, net	34,259	32,980
Inventories	61,436	49,215
Prepaid expenses and other current assets	3,945	5,700
Total current assets	275,273	291,219
Restricted cash	3,329	3,329
Property and equipment, net	9,492	13,273
Operating lease right-of-use assets	4,312	5,375
Other assets	484	605
Total assets	<u>\$ 292,890</u>	<u>\$ 313,801</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,295	\$ 5,827
Accrued compensation and related benefits	14,719	19,005
Accrued expenses and other current liabilities	6,749	13,459
Accrued warranty liability	2,156	3,712
Deferred revenue, current	12,766	11,727
Operating lease liabilities, current	1,745	1,593
Total current liabilities	42,430	55,323
Accrued interest	2,222	896
Deferred revenue	77	101
Operating lease liabilities	3,157	4,482
Term loans	197,182	130,113
Total liabilities	<u>245,068</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 September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of September 30, 2024 and December 31, 2023; 52,538 and 50,317 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	52	50
Additional paid-in capital	1,111,503	1,084,515
Accumulated other comprehensive income	352	68
Accumulated deficit	(1,064,085)	(961,747)
Total stockholders' equity	<u>47,822</u>	<u>122,886</u>
Total liabilities and stockholders' equity	<u>\$ 292,890</u>	<u>\$ 313,801</u>

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

	Nine Months Ended September 30,	
	2024	2023
Net cash used in operating activities	\$ (99,815)	\$ (106,931)
Net cash (used in) provided by investing activities	(4,215)	59,601
Net cash provided by financing activities	68,808	10,423
Net decrease in cash, cash equivalents and restricted cash	(35,222)	(36,907)
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 ⁽¹⁾	\$ 36,616	\$ 39,626

⁽¹⁾ 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):

	September 30,	
	2024	2023
Cash and cash equivalents	\$ 33,287	\$ 36,297
Restricted cash	3,329	3,329
Total cash, cash equivalents and restricted cash *	\$ 36,616	\$ 39,626

* The total cash, including restricted cash, cash equivalents and investment securities as of September 30, 2024 was \$179.0 million; compared to \$197.3 million as of September 30, 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 September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP net loss per share, diluted	\$ (0.55)	\$ (0.93)	\$ (1.98)	\$ (2.72)
Stock-based compensation expense	0.13	0.22	0.47	0.60
Severance and related charges, net	0.03	—	0.07	—
Non-GAAP net loss per share, diluted	<u>\$ (0.39)</u>	<u>\$ (0.71)</u>	<u>\$ (1.44)</u>	<u>\$ (2.12)</u>

Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP net loss, diluted	\$ (27,940)	\$ (46,180)	\$ (102,338)	\$ (134,197)
Stock-based compensation expense	6,388	10,893	24,411	29,536
Severance and related charges, net	1,371	—	3,797	—
Non-GAAP net loss, diluted	<u>\$ (20,181)</u>	<u>\$ (35,287)</u>	<u>\$ (74,130)</u>	<u>\$ (104,661)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
GAAP gross profit	\$ 9,820	\$ 7,157	\$ 27,817	\$ 21,288
Stock-based compensation expense	296	620	1,092	1,381
Severance and related charges, net	317	—	518	—
Non-GAAP gross profit	<u>\$ 10,433</u>	<u>\$ 7,777</u>	<u>\$ 29,427</u>	<u>\$ 22,669</u>
GAAP gross margin	34.3 %	23.6 %	33.0 %	21.3 %
Stock-based compensation expense	1.0	2.0	1.3	1.4
Severance and related charges, net	1.1	—	0.6	—
Non-GAAP gross margin	<u>36.4 %</u>	<u>25.6 %</u>	<u>34.9 %</u>	<u>22.7 %</u>
GAAP research and development expense	\$ 8,139	\$ 16,076	\$ 30,508	\$ 44,775
Stock-based compensation expense	(1,400)	(2,793)	(6,025)	(8,232)
Severance and related charges, net	(161)	—	(1,124)	—
Non-GAAP research and development expense	<u>\$ 6,578</u>	<u>\$ 13,283</u>	<u>\$ 23,359</u>	<u>\$ 36,543</u>
GAAP sales and marketing expense	\$ 15,417	\$ 24,720	\$ 54,593	\$ 74,038
Stock-based compensation expense	(945)	(3,765)	(4,898)	(9,908)
Severance and related charges, net	(873)	—	(1,765)	—
Non-GAAP sales and marketing expense	<u>\$ 13,599</u>	<u>\$ 20,955</u>	<u>\$ 47,930</u>	<u>\$ 64,130</u>
GAAP general and administrative expense	\$ 10,103	\$ 11,815	\$ 34,231	\$ 34,892
Stock-based compensation expense	(3,747)	(3,715)	(12,396)	(10,015)
Severance and related charges, net	(20)	—	(390)	—
Non-GAAP general and administrative expense	<u>\$ 6,336</u>	<u>\$ 8,100</u>	<u>\$ 21,445</u>	<u>\$ 24,877</u>
GAAP total operating expense	\$ 33,659	\$ 52,611	\$ 119,332	\$ 153,705
Stock-based compensation expense	(6,092)	(10,273)	(23,319)	(28,155)
Severance and related charges, net	(1,054)	—	(3,279)	—
Non-GAAP total operating expense	<u>\$ 26,513</u>	<u>\$ 42,338</u>	<u>\$ 92,734</u>	<u>\$ 125,550</u>

