
**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): February 16, 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 February 21, 2024, Outset Medical, Inc. (the “Company”) issued a press release and will hold its fourth quarter and full year 2023 earnings conference call announcing the Company’s financial results for the quarter and year ended December 31, 2023. 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.

On February 16, 2024, Steve Williamson informed the Company of his decision to depart from the Company and his role as Chief Commercial Officer, effective March 1, 2024, to become the CEO of another publicly traded medical device company. Mr. Williamson’s departure is not due to any dispute or disagreement with the Company or its management.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release entitled “Outset Medical Reports Fourth Quarter and Full Year 2023 Financial Results” dated February 21, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

Outset Medical Reports Fourth Quarter and Full Year 2023 Financial Results

San Jose, CA – February 21, 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 fourth quarter and full year ended December 31, 2023.

Fourth Quarter, Year-End Results, and Recent Highlights

- Recorded net revenue of \$30.5 million in the fourth quarter, bringing 2023 revenue to \$130.4 million, a 13% increase compared to \$115.4 million in 2022.
- Increased gross margin in the fourth quarter by nearly 900 basis points from the prior-year period. Fourth quarter gross margin reached 25.3% (26.7% on a non-GAAP basis) compared to 16.5% (17.1% on a non-GAAP basis) in the fourth quarter of 2022. Gross margin for the full year was 22.2% (23.6% on a non-GAAP basis) compared to 15.5% (16.1% on a non-GAAP basis) in 2022.
- As previously reported, recurring revenue consisting of Tablo consumables and services, exceeded 50% of total revenue in 2023, and the Tablo installed base reached 5,350 consoles exiting 2023, including approximately 4,050 with acute- and sub-acute care providers and 1,300 with home providers.

“As we announced in January, our results for the fourth quarter and full year reflect the scale we have built in the acute setting and progress we are making to expand Tablo’s use at home, with our growth in both end markets contributing to a 34% increase in the Tablo installed base and nearly 50% growth in consumable revenue,” said Leslie Trigg, Chair and Chief Executive Officer of Outset. “We exited 2023 with a record 50% recurring revenue, fourth-quarter gross margin expanding nearly 9 percentage points, and a strong balance sheet to continue to fund our growth. We are proud of the difference Tablo and our team made in 2023 to help providers save substantially on the cost to deliver life-sustaining dialysis, and patients regain control that has been historically lost with their diagnosis.”

Fourth Quarter 2023 Financial Results

Revenue for the fourth quarter of 2023 was \$30.5 million, representing a decrease of 4.7% compared to \$32.0 million in the fourth quarter of 2022. Product revenue was \$22.9 million, representing a decrease of 13.2% compared to \$26.4 million in the fourth quarter of 2022. Service and other revenue was \$7.6 million, representing an increase of 34.9% compared to \$5.6 million in the fourth quarter of 2022.

Total gross profit was \$7.7 million, compared to \$5.3 million for the fourth quarter of 2022. Total gross margin was 25.3%, compared to 16.5% in the fourth quarter of 2022. On a non-GAAP basis, gross margin improved to 26.7% from 17.1% in the fourth quarter of 2022. Product gross profit was \$8.3 million, compared to \$4.3 million of product gross profit in the fourth quarter of 2022. Product gross margin was 36.3%, compared to 16.4% in the fourth quarter of 2022. Service and other gross loss was (\$0.6) million, compared to \$1.0 million of service and other gross profit in the fourth quarter of 2022. Service and other gross margin was (7.8)%, compared to 17.0% in the fourth quarter of 2022.

Operating expenses were \$45.1 million, including research and development (R&D) expenses of \$12.5 million, sales and marketing (S&M) expenses of \$22.2 million, and general and administrative (G&A) expenses of \$10.3 million. This compared to operating expenses of \$45.1 million, including R&D expenses of \$11.4 million, S&M expenses of \$23.6 million, and G&A expenses of \$10.0 million in the fourth quarter of 2022.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$36.4 million, including R&D expenses of \$10.2 million, S&M expenses of \$19.7 million, and G&A expenses of \$6.5 million.

Net loss was (\$38.6) million, or (\$0.77) per share, compared to net loss of (\$41.4) million, or (\$0.86) per share, for the same period in 2022. On a non-GAAP basis, net loss was (\$29.5) million, or (\$0.59) per share, compared to non-GAAP net loss of (\$34.1) million, or (\$0.71) per share for the same period in 2022.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$206.7 million as of December 31, 2023, compared to \$290.8 million as of December 31, 2022.

Full Year 2023 Financial Results

Revenue for 2023 was \$130.4 million, representing an increase of 13.0% compared to \$115.4 million for 2022. Product revenue was \$103.5 million, representing an increase of 10.9% compared to \$93.4 million for 2022. Service and other revenue was \$26.8 million, representing an increase of 22.1% compared to \$22.0 million for 2022.

Total gross profit was \$29.0 million, compared to \$17.8 million for 2022. Total gross margin was 22.2%, compared to 15.5% in 2022. On a non-GAAP basis, gross margin improved to 23.6% from 16.1% in 2022. Product gross profit was \$29.1 million, compared to \$10.9 million of product gross profit in 2022. Product gross margin was 28.1%, compared to 11.6% in 2022. Service and other gross loss was (\$0.1) million, compared to \$7.0 million of service and other gross profit in 2022. Service and other gross margin was (0.3)%, compared to 31.6% in 2022.

Operating expenses were \$198.8 million, including R&D expenses of \$57.3 million, S&M expenses of \$96.2 million, and G&A expenses of \$45.2 million. This compared to operating expenses of \$178.9 million, including R&D expenses of \$48.9 million, S&M expenses of \$89.5 million, and G&A expenses of \$40.5 million for 2022.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$161.9 million, including R&D expenses of \$46.8 million, S&M expenses of \$83.8 million, and G&A expenses of \$31.4 million.

Net loss was (\$172.8) million, or (\$3.48) per share, compared to a net loss of (\$163.0) million, or (\$3.38) per share, for 2022. On a non-GAAP basis, net loss was (\$134.2) million, or (\$2.70) per share, compared to a non-GAAP net loss of (\$135.8) million, or (\$2.82) per share for 2022.

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 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, February 21, 2024, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its fourth quarter and full year 2023 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. 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 possible or assumed future results of operations and financial position, including expectations

regarding projected revenues, 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.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Revenue:				
Product revenue	\$ 22,897	\$ 26,364	\$ 103,537	\$ 93,388
Service and other revenue	7,610	5,643	26,839	21,987
Total revenue	30,507	32,007	130,376	115,375
Cost of revenue:				
Cost of product revenue ⁽²⁾	14,588	22,050	74,454	82,510
Cost of service and other revenue	8,207	4,684	26,922	15,032
Total cost of revenue	22,795	26,734	101,376	97,542
Gross profit ⁽¹⁾	7,712	5,273	29,000	17,833
Gross margin ⁽¹⁾	25.3 %	16.5 %	22.2 %	15.5 %
Operating expenses:				
Research and development ⁽²⁾	12,532	11,444	57,307	48,855
Sales and marketing ⁽²⁾	22,194	23,631	96,232	89,482
General and administrative ⁽²⁾	10,339	10,022	45,231	40,515
Total operating expenses	45,065	45,097	198,770	178,852
Loss from operations	(37,353)	(39,824)	(169,770)	(161,019)
Interest income and other income, net	2,282	1,907	10,171	3,291
Interest expense	(3,417)	(2,096)	(12,675)	(3,566)
Loss on extinguishment of term loan	—	(1,367)	—	(1,367)
Loss before provision for income taxes	(38,488)	(41,380)	(172,274)	(162,661)
Provision for income taxes	112	64	523	295
Net loss	\$ (38,600)	\$ (41,444)	\$ (172,797)	\$ (162,956)
Net loss per share, basic and diluted	\$ (0.77)	\$ (0.86)	\$ (3.48)	\$ (3.38)
Shares used in computing net loss per share, basic and diluted	50,254	48,375	49,588	48,161

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

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Gross profit				
Product revenue	\$ 8,309	\$ 4,314	\$ 29,083	\$ 10,878
Service and other revenue	(597)	959	(83)	6,955
Total gross profit	\$ 7,712	\$ 5,273	\$ 29,000	\$ 17,833
Gross margin				
Product revenue	36.3 %	16.4 %	28.1 %	11.6 %
Service and other revenue	(7.8) %	17.0 %	(0.3) %	31.6 %
Total gross margin	25.3 %	16.5 %	22.2 %	15.5 %

⁽²⁾ Include stock-based compensation expense as follows:

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
Cost of revenue	\$ 424	\$ 208	\$ 1,805	\$ 701
Research and development	2,306	1,960	10,538	6,845
Sales and marketing	2,511	2,829	12,419	10,269
General and administrative	3,857	2,356	13,872	9,388
Total stock-based compensation expense	\$ 9,098	\$ 7,353	\$ 38,634	\$ 27,203

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

	December 31,	
	2023	2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 68,509	\$ 73,222
Short-term investments	134,815	214,280
Accounts receivable, net	32,980	28,070
Inventories	49,215	51,476
Prepaid expenses and other current assets	5,700	6,597
Total current assets	291,219	373,645
Restricted cash	3,329	3,311
Property and equipment, net	13,273	15,876
Operating lease right-of-use assets	5,375	6,117
Other assets	605	1,166
Total assets	\$ 313,801	\$ 400,115
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 5,827	\$ 603
Accrued compensation and related benefits	19,005	21,519
Accrued expenses and other current liabilities	13,459	16,227
Accrued warranty liability	3,712	3,620
Deferred revenue, current	11,727	8,662
Operating lease liabilities, current	1,593	1,318
Total current liabilities	55,323	51,949
Accrued interest	896	113
Deferred revenue	101	151
Operating lease liabilities	4,482	5,576
Term loans	130,113	96,336
Total liabilities	190,915	154,125
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of December 31, 2023 and 2022	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of December 31, 2023 and 2022; 50,317 and 48,465 shares issued and outstanding as of December 31, 2023 and 2022, respectively	50	48
Additional paid-in capital	1,084,515	1,035,456
Accumulated other comprehensive loss	68	(564)
Accumulated deficit	(961,747)	(788,950)
Total stockholders' equity	122,886	245,990
Total liabilities and stockholders' equity	\$ 313,801	\$ 400,115

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

	Years Ended December 31,	
	2023	2022
Net cash used in operating activities	\$ (131,373)	\$ (145,729)
Net cash provided by (used in) investing activities	83,026	(66,295)
Net cash provided by financing activities	43,652	72,898
Net decrease in cash, cash equivalents and restricted cash	(4,695)	(139,126)
Cash, cash equivalents and restricted cash at beginning of the period	76,533	215,659
Cash, cash equivalents and restricted cash at end of the period ⁽¹⁾	\$ 71,838	\$ 76,533

⁽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):

	December 31,	
	2023	2022
Cash and cash equivalents	\$ 68,509	\$ 73,222
Restricted cash	3,329	3,311
Total cash, cash equivalents and restricted cash*	\$ 71,838	\$ 76,533

* The total cash, including restricted cash, cash equivalents and investment securities as of December 31, 2023 was \$206.7 million; compared to \$290.8 million as of December 31, 2022.

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 December 31,		Years Ended December 31,	
	2023	2022	2023	2022
GAAP net loss per share, diluted	\$ (0.77)	\$ (0.86)	\$ (3.48)	\$ (3.38)
Stock-based compensation expense	0.18	0.15	0.78	0.56
Non-GAAP net loss per share, diluted	<u>\$ (0.59)</u>	<u>\$ (0.71)</u>	<u>\$ (2.70)</u>	<u>\$ (2.82)</u>

Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
GAAP net loss, diluted	\$ (38,600)	\$ (41,444)	\$ (172,797)	\$ (162,956)
Stock-based compensation expense	9,098	7,353	38,634	27,203
Non-GAAP net loss, diluted	<u>\$ (29,502)</u>	<u>\$ (34,091)</u>	<u>\$ (134,163)</u>	<u>\$ (135,753)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended December 31,		Years Ended December 31,	
	2023	2022	2023	2022
GAAP gross profit	\$ 7,712	\$ 5,273	\$ 29,000	\$ 17,833
Stock-based compensation expense	424	208	1,805	701
Non-GAAP gross profit	<u>\$ 8,136</u>	<u>\$ 5,481</u>	<u>\$ 30,805</u>	<u>\$ 18,534</u>
GAAP gross margin	25.3 %	16.5 %	22.2 %	15.5 %
Stock-based compensation expense	1.4	0.6	1.4	0.6
Non-GAAP gross margin	<u>26.7 %</u>	<u>17.1 %</u>	<u>23.6 %</u>	<u>16.1 %</u>
GAAP research and development expense	\$ 12,532	\$ 11,444	\$ 57,307	\$ 48,855
Stock-based compensation expense	(2,306)	(1,960)	(10,538)	(6,845)
Non-GAAP research and development expense	<u>\$ 10,226</u>	<u>\$ 9,484</u>	<u>\$ 46,769</u>	<u>\$ 42,010</u>
GAAP sales and marketing expense	\$ 22,194	\$ 23,631	\$ 96,232	\$ 89,482
Stock-based compensation expense	(2,511)	(2,829)	(12,419)	(10,269)
Non-GAAP sales and marketing expense	<u>\$ 19,683</u>	<u>\$ 20,802</u>	<u>\$ 83,813</u>	<u>\$ 79,213</u>
GAAP general and administrative expense	\$ 10,339	\$ 10,022	\$ 45,231	\$ 40,515
Stock-based compensation expense	(3,857)	(2,356)	(13,872)	(9,388)
Non-GAAP general and administrative expense	<u>\$ 6,482</u>	<u>\$ 7,666</u>	<u>\$ 31,359</u>	<u>\$ 31,127</u>
GAAP total operating expense	\$ 45,065	\$ 45,097	\$ 198,770	\$ 178,852
Stock-based compensation expense	(8,674)	(7,145)	(36,829)	(26,502)
Non-GAAP total operating expense	<u>\$ 36,391</u>	<u>\$ 37,952</u>	<u>\$ 161,941</u>	<u>\$ 152,350</u>

