

**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 3, 2023

Outset Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39513

(Commission File Number)

20-0514392
(IRS Employer
Identification No.)

**3052 Orchard Dr.,
San Jose, California**
(Address of Principal Executive Offices)

95134
(Zip Code)

Registrant's Telephone Number, Including Area Code: (669) 231-8200

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 3, 2023, Outset Medical, Inc. (the “Company”) issued a press release and will hold its first quarter 2023 earnings conference call announcing the Company’s financial results for the quarter ended March 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 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release entitled “Outset Medical Reports First Quarter 2023 Financial Results” dated May 3, 2023
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 3, 2023

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

Outset Medical Reports First Quarter 2023 Financial Results

Increases Revenue and Gross Margin Guidance for 2023

San Jose, CA – May 3, 2023 – 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, 2023.

Recent Highlights

- Recorded net revenue of \$33.5 million in the first quarter, a 9.5% increase compared to \$30.6 million in the first quarter of 2022, and a 4.6% increase compared to \$32.0 million in the fourth quarter of 2022
- Achieved gross margin for the first quarter of 19.2% (20.3% on a non-GAAP basis), compared to 14.5% (14.8% on a non-GAAP basis) in the first quarter of 2022
- Added more than 30 new hospital sites during the first quarter as part of Outset’s land and expand commercial strategy, the largest quarterly growth in new sites since 2021
- Presented five data sets at the National Kidney Foundation Spring Clinical Meetings highlighting the clinical and financial benefits of home hemodialysis and other pertinent topics related to kidney disease

“We had a strong start to 2023, with revenue growth ahead of our expectations and gross margins expanding for the 8th consecutive quarter,” said Leslie Trigg, Chair and Chief Executive Officer. “The momentum we had exiting 2022 carried through the first quarter of 2023 with the benefits of Tablo continuing to resonate with acute-care and home providers.”

First Quarter 2023 Financial Results

Revenue for the first quarter of 2023 was \$33.5 million, representing an increase of 9.5% compared to \$30.6 million in the first quarter of 2022. Product revenue was \$27.8 million, representing an increase of 8.2% compared to \$25.7 million in the first quarter of 2022. Service and other revenue was \$5.7 million, representing an increase of 16.4% compared to \$4.9 million in the first quarter of 2022.

Total gross profit was \$6.4 million, compared to \$4.4 million for the first quarter of 2022. Total gross margin was 19.2%, compared to 14.5% in the first quarter of 2022. On a non-GAAP basis, gross margin improved to 20.3% from 14.8% in the first quarter of 2022. Product gross profit was \$7.0 million, compared to \$2.6 million of product gross profit in the first quarter of 2022. Product gross margin was 25.1%, compared to 10.0% in the first quarter of 2022. Service and other gross loss was (\$0.5) million, compared to \$1.9 million of service and other gross profit in the first quarter of 2022. Service and other gross margin was (9.4)%, compared to 38.6% in the first quarter of 2022.

Operating expenses were \$49.9 million, including research and development (R&D) expenses of \$13.8 million, sales and marketing (S&M) expenses of \$24.3 million, and general and administrative (G&A) expenses of \$11.8 million. This compared to operating expenses of \$40.9 million, including R&D expenses of \$10.8 million, S&M expenses of \$20.4 million, and G&A expenses of \$9.7 million in the first quarter of 2022.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$41.7 million, including R&D expenses of \$11.2 million, S&M expenses of \$21.7 million, and G&A expenses of \$8.8 million.

Net loss was (\$44.0) million, or (\$0.90) per share, compared to net loss of (\$36.9) million, or (\$0.78) per share, for the same period in 2022. On a non-GAAP basis, net loss was (\$35.4) million, or (\$0.72) per share, compared to non-GAAP net loss of (\$31.9) million, or (\$0.67) per share for the same period in 2022.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$252.5 million as of March 31, 2023.

Full Year 2023 Financial Guidance

Outset now projects revenue for 2023 to range from \$144 million to \$150 million, which represents approximately 25% to 30% growth over the Company’s fiscal year 2022 revenue. This updated guidance compares to prior 2023 revenue guidance

of \$140 million to \$150 million. In addition, the Company expects gross margin for the year to be in the low-20% range, up from its prior guidance of approximately 20%, and exiting the fourth quarter in the mid-20% range.

Webcast and Conference Call Details

Outset will host a conference call today, May 3, 2023, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its first quarter 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 (including sales into the home market and such sales as a percentage of 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 reduce the cost of producing and shipping our products, expand gross margins, further secure supply continuity and otherwise mitigate supply chain challenges and its ability to achieve projected cost reductions and other anticipated benefits from these initiatives at the levels or within the timeframe estimated; 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.

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

	Three Months Ended	
	March 31,	
	2023	2022
Revenue:		
Product revenue	\$ 27,779	\$ 25,664
Service and other revenue	5,688	4,886
Total revenue	33,467	30,550
Cost of revenue:		
Cost of product revenue ⁽²⁾	20,817	23,110
Cost of service and other revenue	6,222	2,998
Total cost of revenue	27,039	26,108
Gross profit ⁽¹⁾	6,428	4,442
Gross margin ⁽¹⁾	19.2 %	14.5 %
Operating expenses:		
Research and development ⁽²⁾	13,793	10,831
Sales and marketing ⁽²⁾	24,333	20,377
General and administrative ⁽²⁾	11,787	9,709
Total operating expenses	49,913	40,917
Loss from operations	(43,485)	(36,475)
Interest income and other income, net	2,648	120
Interest expense	(2,942)	(422)
Loss before provision for income taxes	(43,779)	(36,777)
Provision for income taxes	192	115
Net loss	\$ (43,971)	\$ (36,892)
Net loss per share, basic and diluted	\$ (0.90)	\$ (0.78)
Shares used in computing net loss per share, basic and diluted	48,783	47,487

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

	Three Months Ended March 31,	
	2023	2022
Gross profit		
Product revenue	\$ 6,962	\$ 2,554
Service and other revenue	(534)	1,888
Total gross profit	<u>\$ 6,428</u>	<u>\$ 4,442</u>
Gross margin		
Product revenue	25.1 %	10.0 %
Service and other revenue	(9.4) %	38.6 %
Total gross margin	19.2 %	14.5 %

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

	Three Months Ended March 31,	
	2023	2022
Cost of revenue	\$ 358	\$ 93
Research and development	2,615	1,158
Sales and marketing	2,598	1,706
General and administrative	2,967	2,049
Total stock-based compensation expense	<u>\$ 8,538</u>	<u>\$ 5,006</u>

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

	March 31, 2023 <u>(Unaudited)</u>	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,386	\$ 73,222
Short-term investments	212,827	214,280
Accounts receivable, net	34,314	28,070
Inventories	47,733	51,476
Prepaid expenses and other current assets	6,015	6,597
Total current assets	337,275	373,645
Restricted cash	3,311	3,311
Property and equipment, net	15,189	15,876
Operating lease right-of-use assets	5,823	6,117
Other assets	1,067	1,166
Total assets	<u>\$ 362,665</u>	<u>\$ 400,115</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,988	\$ 603
Accrued compensation and related benefits	14,419	21,519
Accrued expenses and other current liabilities	13,893	16,227
Accrued warranty liability	3,569	3,620
Deferred revenue, current	9,038	8,662
Operating lease liabilities, current	1,361	1,318
Total current liabilities	44,268	51,949
Accrued interest	295	113
Deferred revenue	116	151
Operating lease liabilities	5,220	5,576
Term loan	96,480	96,336
Total liabilities	<u>146,379</u>	<u>154,125</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, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of March 31, 2023 and December 31, 2022; 49,216 and 48,465 shares issued and outstanding as of March 31, 2023 and December 31, 2022, respectively	49	48
Additional paid-in capital	1,049,271	1,035,456
Accumulated other comprehensive loss	(113)	(564)
Accumulated deficit	(832,921)	(788,950)
Total stockholders' equity	<u>216,286</u>	<u>245,990</u>
Total liabilities and stockholders' equity	<u>\$ 362,665</u>	<u>\$ 400,115</u>

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

	Three Months Ended March 31,	
	2023	2022
Net cash used in operating activities	\$ (44,756)	\$ (38,335)
Net cash provided by (used in) investing activities	2,643	(33,390)
Net cash provided by financing activities	5,277	3,723
Net decrease in cash, cash equivalents and restricted cash	(36,836)	(68,002)
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⁾	\$ 39,697	\$ 147,657

⁽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):

	March 31,	
	2023	2022
Cash and cash equivalents	\$ 36,386	\$ 114,346
Restricted cash	3,311	33,311
Total cash, cash equivalents and restricted cash*	\$ 39,697	\$ 147,657

* The total cash, including restricted cash, cash equivalents and investment securities as of March 31, 2023 was \$252.5 million; compared to \$335.6 million as of March 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	
	March 31,	
	2023	2022
GAAP net loss per share, diluted	\$ (0.90)	\$ (0.78)
Stock-based compensation expense	0.18	0.11
Non-GAAP net loss per share, diluted	<u>\$ (0.72)</u>	<u>\$ (0.67)</u>

Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended	
	March 31,	
	2023	2022
GAAP net loss, diluted	\$ (43,971)	\$ (36,892)
Stock-based compensation expense	8,538	5,006
Non-GAAP net loss, diluted	<u>\$ (35,433)</u>	<u>\$ (31,886)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended	
	March 31,	
	2023	2022
GAAP gross profit	\$ 6,428	\$ 4,442
Stock-based compensation expense	358	93
Non-GAAP gross profit	<u>\$ 6,786</u>	<u>\$ 4,535</u>
GAAP gross margin	19.2 %	14.5 %
Stock-based compensation expense	1.1	0.3
Non-GAAP gross margin	<u>20.3 %</u>	<u>14.8 %</u>
GAAP research and development expense	\$ 13,793	\$ 10,831
Stock-based compensation expense	(2,615)	(1,158)
Non-GAAP research and development expense	<u>\$ 11,178</u>	<u>\$ 9,673</u>
GAAP sales and marketing expense	\$ 24,333	\$ 20,377
Stock-based compensation expense	(2,598)	(1,706)
Non-GAAP sales and marketing expense	<u>\$ 21,735</u>	<u>\$ 18,671</u>
GAAP general and administrative expense	\$ 11,787	\$ 9,709
Stock-based compensation expense	(2,967)	(2,049)
Non-GAAP general and administrative expense	<u>\$ 8,820</u>	<u>\$ 7,660</u>
GAAP total operating expense	\$ 49,913	\$ 40,917
Stock-based compensation expense	(8,180)	(4,913)
Non-GAAP total operating expense	<u>\$ 41,733</u>	<u>\$ 36,004</u>

