

**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 2, 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 August 2, 2023, Outset Medical, Inc. (the “Company”) issued a press release and will hold its second quarter 2023 earnings conference call announcing the Company’s financial results for the quarter ended June 30, 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 Second Quarter 2023 Financial Results” dated August 2, 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: August 2, 2023

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

Outset Medical Reports Second Quarter 2023 Financial Results

Sequential Revenue Growth of 8%, Ninth Consecutive Quarter of Gross Margin Expansion

Announces Shipment Pause of TabloCart with Prefiltration Pending 510(k) Clearance

Reiterates 2023 Revenue Range of \$144 Million to \$150 Million

San Jose, CA – August 2, 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 second quarter ended June 30, 2023.

Recent Highlights

- Recorded net revenue of \$36.0 million in the second quarter, a 44% increase compared to \$25.1 million in the second quarter of 2022, and an 8% increase compared to \$33.5 million in the first quarter of 2023.
- Achieved gross margin for the second quarter of 21.4% (22.5% on a non-GAAP basis), compared to 15.1% (15.9% on a non-GAAP basis) in the second quarter of 2022.
- Initiated the first Tablo home dialysis program with one of the country’s largest health systems with plans to expand to multiple U.S. sites.
- Achieved the Company’s goal of signing agreements with the majority of U.S. mid-sized dialysis providers, further expanding its reach to patients who choose to dialyze at home.

“Our momentum entering 2023 carried through the second quarter, led by the strong demand from hospitals due to the value realized from insourcing dialysis with Tablo,” said Leslie Trigg, Chair and Chief Executive Officer. “As important, Tablo’s unique ease of use and flexibility continues to drive patient interest and demand from home-care providers, including traditional acute-care providers.”

The Company also announced it has paused the shipment of TabloCart with Prefiltration, an accessory for the Tablo System, pending the Food and Drug Administration’s clearance of a 510(k) the company plans to submit later this month.

“Since receiving the Warning Letter on July 6, we have made the decision to file a 510(k) for TabloCart with Prefiltration and pause distribution of the product until a 510(k) clearance has been granted,” added Trigg. “As we look ahead to the second half of the year, we expect our strong momentum both in the acute and home end markets to continue to drive the business.”

Second Quarter 2023 Financial Results

Revenue for the second quarter of 2023 was \$36.0 million, representing an increase of 43.8% compared to \$25.1 million in the second quarter of 2022. Product revenue was \$29.3 million, representing an increase of 49.5% compared to \$19.6 million in the second quarter of 2022. Service and other revenue was \$6.7 million, representing an increase of 23.4% compared to \$5.4 million in the second quarter of 2022.

Total gross profit was \$7.7 million, compared to \$3.8 million for the second quarter of 2022. Total gross margin was 21.4%, compared to 15.1% in the second quarter of 2022. On a non-GAAP basis, gross margin improved to 22.5% from 15.9% in the second quarter of 2022. Product gross profit was \$7.1 million, compared to \$1.9 million of product gross profit in the second quarter of 2022. Product gross margin was 24.3%, compared to 9.7% in the second quarter of 2022. Service and other gross profit was \$0.6 million, compared to \$1.9 million of service and other gross profit in the second quarter of 2022. Service and other gross margin was 8.7%, compared to 34.6% in the second quarter of 2022.

Operating expenses were \$51.2 million, including research and development (R&D) expenses of \$14.9 million, sales and marketing (S&M) expenses of \$25.0 million, and general and administrative (G&A) expenses of \$11.3 million. This compared to operating expenses of \$47.5 million, including R&D expenses of \$13.5 million, S&M expenses of \$23.2 million, and G&A expenses of \$10.8 million in the second quarter of 2022.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$41.5 million, including R&D expenses of \$12.1 million, S&M expenses of \$21.4 million, and G&A expenses of \$8.0 million.

Net loss was (\$44.0) million, or (\$0.90) per share, compared to net loss of (\$43.8) million, or (\$0.92) per share, for the same period in 2022. On a non-GAAP basis, net loss was (\$33.9) million, or (\$0.69) per share, compared to non-GAAP net loss of (\$36.4) million, or (\$0.77) per share for the same period in 2022.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$226.1 million as of June 30, 2023.

Full Year 2023 Financial Guidance

Outset reiterated its 2023 revenue guidance range of \$144 million to \$150 million, and now expects to be at the low end of this range as a result of the shipment pause for TabloCart with Prefiltration. The Company reaffirmed its gross margin guidance for the year to be in the low-20% range, exiting the fourth quarter in the mid-20% range.

Webcast and Conference Call Details

Outset will host a conference call today, August 2, 2023, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its second 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, 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; our 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.

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	\$ 29,330	\$ 19,621	\$ 57,109	\$ 45,285
Service and other revenue	6,710	5,436	12,398	10,322
Total revenue	36,040	25,057	69,507	55,607
Cost of revenue:				
Cost of product revenue ⁽²⁾	22,212	17,718	43,029	40,828
Cost of service and other revenue	6,125	3,557	12,347	6,555
Total cost of revenue	28,337	21,275	55,376	47,383
Gross profit ⁽¹⁾	7,703	3,782	14,131	8,224
Gross margin ⁽¹⁾	21.4 %	15.1 %	20.3 %	14.8 %
Operating expenses:				
Research and development ⁽²⁾	14,906	13,521	28,699	24,352
Sales and marketing ⁽²⁾	24,985	23,198	49,318	43,575
General and administrative ⁽²⁾	11,290	10,784	23,077	20,493
Total operating expenses	51,181	47,503	101,094	88,420
Loss from operations	(43,478)	(43,721)	(86,963)	(80,196)
Interest income and other income, net	2,668	459	5,316	579
Interest expense	(3,103)	(481)	(6,045)	(903)
Loss before provision for income taxes	(43,913)	(43,743)	(87,692)	(80,520)
Provision for income taxes	133	96	325	211
Net loss	\$ (44,046)	\$ (43,839)	\$ (88,017)	\$ (80,731)
Net loss per share, basic and diluted	\$ (0.90)	\$ (0.92)	\$ (1.79)	\$ (1.69)
Shares used in computing net loss per share, basic and diluted	48,951	47,882	49,085	47,686

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Gross profit				
Product revenue	\$ 7,118	\$ 1,903	\$ 14,080	\$ 4,457
Service and other revenue	585	1,879	51	3,767
Total gross profit	\$ 7,703	\$ 3,782	\$ 14,131	\$ 8,224
Gross margin				
Product revenue	24.3 %	9.7 %	24.7 %	9.8 %
Service and other revenue	8.7 %	34.6 %	0.4 %	36.5 %
Total gross margin	21.4 %	15.1 %	20.3 %	14.8 %

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Cost of revenue	\$ 403	\$ 190	\$ 761	\$ 283
Research and development	2,824	1,808	5,439	2,966
Sales and marketing	3,545	2,864	6,143	4,570
General and administrative	3,333	2,552	6,300	4,601
Total stock-based compensation expense	\$ 10,105	\$ 7,414	\$ 18,643	\$ 12,420

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

	June 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,388	\$ 73,222
Short-term investments	186,403	214,280
Accounts receivable, net	36,902	28,070
Inventories	44,495	51,476
Prepaid expenses and other current assets	5,216	6,597
Total current assets	309,404	373,645
Restricted cash	3,329	3,311
Property and equipment, net	14,539	15,876
Operating lease right-of-use assets	6,042	6,117
Other assets	1,128	1,166
Total assets	<u>\$ 334,442</u>	<u>\$ 400,115</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,217	\$ 603
Accrued compensation and related benefits	17,461	21,519
Accrued expenses and other current liabilities	12,650	16,227
Accrued warranty liability	4,168	3,620
Deferred revenue, current	10,854	8,662
Operating lease liabilities, current	1,474	1,318
Total current liabilities	48,824	51,949
Accrued interest	484	113
Deferred revenue	89	151
Operating lease liabilities	5,308	5,576
Term loan	96,629	96,336
Total liabilities	<u>151,334</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 June 30, 2023 and December 31, 2022	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of June 30, 2023 and December 31, 2022; 49,629 and 48,465 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	50	48
Additional paid-in capital	1,060,418	1,035,456
Accumulated other comprehensive loss	(393)	(564)
Accumulated deficit	(876,967)	(788,950)
Total stockholders' equity	183,108	245,990
Total liabilities and stockholders' equity	<u>\$ 334,442</u>	<u>\$ 400,115</u>

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

	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	\$ (72,932)	\$ (76,910)
Net cash provided by (used in) investing activities	29,796	(34,706)
Net cash provided by financing activities	6,320	4,765
Net decrease in cash, cash equivalents and restricted cash	(36,816)	(106,851)
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⁾	<u>\$ 39,717</u>	<u>\$ 108,808</u>

⁽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):

	June 30,	
	2023	2022
Cash and cash equivalents	\$ 36,388	\$ 75,497
Restricted cash	3,329	33,311
Total cash, cash equivalents and restricted cash*	<u>\$ 39,717</u>	<u>\$ 108,808</u>

* The total cash, including restricted cash, cash equivalents and investment securities as of June 30, 2023 was \$226.1 million; compared to \$295.4 million as of June 30, 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		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
GAAP net loss per share, diluted	\$ (0.90)	\$ (0.92)	\$ (1.79)	\$ (1.69)
Stock-based compensation expense	0.21	0.15	0.38	0.26
Non-GAAP net loss per share, diluted	<u>\$ (0.69)</u>	<u>\$ (0.77)</u>	<u>\$ (1.41)</u>	<u>\$ (1.43)</u>

Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
GAAP net loss, diluted	\$ (44,046)	\$ (43,839)	\$ (88,017)	\$ (80,731)
Stock-based compensation expense	10,105	7,414	18,643	12,420
Non-GAAP net loss, diluted	<u>\$ (33,941)</u>	<u>\$ (36,425)</u>	<u>\$ (69,374)</u>	<u>\$ (68,311)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
GAAP gross profit	\$ 7,703	\$ 3,782	\$ 14,131	\$ 8,224
Stock-based compensation expense	403	190	761	283
Non-GAAP gross profit	<u>\$ 8,106</u>	<u>\$ 3,972</u>	<u>\$ 14,892</u>	<u>\$ 8,507</u>
GAAP gross margin	21.4 %	15.1 %	20.3 %	14.8 %
Stock-based compensation expense	1.1	0.8	1.1	0.5
Non-GAAP gross margin	<u>22.5 %</u>	<u>15.9 %</u>	<u>21.4 %</u>	<u>15.3 %</u>
GAAP research and development expense	\$ 14,906	\$ 13,521	\$ 28,699	\$ 24,352
Stock-based compensation expense	(2,824)	(1,808)	(5,439)	(2,966)
Non-GAAP research and development expense	<u>\$ 12,082</u>	<u>\$ 11,713</u>	<u>\$ 23,260</u>	<u>\$ 21,386</u>
GAAP sales and marketing expense	\$ 24,985	\$ 23,198	\$ 49,318	\$ 43,575
Stock-based compensation expense	(3,545)	(2,864)	(6,143)	(4,570)
Non-GAAP sales and marketing expense	<u>\$ 21,440</u>	<u>\$ 20,334</u>	<u>\$ 43,175</u>	<u>\$ 39,005</u>
GAAP general and administrative expense	\$ 11,290	\$ 10,784	\$ 23,077	\$ 20,493
Stock-based compensation expense	(3,333)	(2,552)	(6,300)	(4,601)
Non-GAAP general and administrative expense	<u>\$ 7,957</u>	<u>\$ 8,232</u>	<u>\$ 16,777</u>	<u>\$ 15,892</u>
GAAP total operating expense	\$ 51,181	\$ 47,503	\$ 101,094	\$ 88,420
Stock-based compensation expense	(9,702)	(7,224)	(17,882)	(12,137)
Non-GAAP total operating expense	<u>\$ 41,479</u>	<u>\$ 40,279</u>	<u>\$ 83,212</u>	<u>\$ 76,283</u>

