

**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 1, 2022

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 1, 2022, Outset Medical, Inc. (the “Company”) issued a press release and will hold its second quarter 2022 earnings conference call announcing the Company’s financial results for the quarter ended June 30, 2022, as well as full year 2022 guidance. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated into this Item 2.02 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.

Item 8.01 Other Events.

As previously disclosed, on June 13, 2022, the Company announced its implementation of a shipment hold on the distribution of its Tablo Hemodialysis System for home use pending the Food and Drug Administration’s (“FDA”) review and clearance of a 510(k) application the Company submitted for changes made since the device’s original March 2020 clearance.

On August 1, 2022, the Company also announced that the FDA has cleared its 510(k) application of Tablo for patient use in the home and that the Company has resumed shipments of Tablo for home use.

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 the Company’s possible or assumed future results of operations and financial position, including projected revenues and gross margin. 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 report and the exhibit attached hereto can be found in the Risk Factors section of the Company’s public filings with the Securities and Exchange Commission (“SEC”), 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release entitled “Outset Medical Resumes Shipment of Tablo Systems for Home Use, Reports Second Quarter 2022 Financial Results and Provides 2022 Guidance” dated August 1, 2022
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 1, 2022

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

**Outset Medical Resumes Shipment of Tablo Systems for Home Use,
Reports Second Quarter 2022 Financial Results and Provides 2022 Guidance**

Investor Webcast and Conference Call Scheduled for 5:00 p.m. EST

San Jose, CA – August 1, 2022 – 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 announced clearance by the Food and Drug Administration of its previously disclosed 510(k) submission and resumption of Tablo® Hemodialysis System shipments for home use.

The Company also reported financial results for the second quarter ended June 30, 2022 and provided financial guidance for 2022. Revenue for the second quarter totaled \$25.1 million, in line with guidance provided on June 13, 2022. Gross margin for the second quarter was 15.1%, compared to 4.2% in the second quarter of 2021 and 14.5% in the first quarter of 2022.

“We are pleased to begin supporting new patients in the home again and helping them achieve autonomy and control over where and when they dialyze,” said Leslie Trigg, Chair and Chief Executive Officer. “As we look to the second half of the year, we see no change in underlying demand for Tablo. However, we have reflected in our guidance the staffing and inflationary pressures our provider customers are facing, as well as the work we need to do to regain commercial momentum following release of the Tablo ship hold.”

Second Quarter 2022 Financial Results

Revenue for the second quarter of 2022 was \$25.1 million, compared to \$25.2 million in the second quarter of 2021. Product revenue for the second quarter of 2022 was \$19.6 million, representing a decrease of 4.9% compared to \$20.6 million in the second quarter of 2021. Service and other revenue for the second quarter of 2022 was \$5.4 million, representing an increase of 18.5% compared to \$4.6 million in the second quarter of 2021.

Total gross profit for the second quarter of 2022 was \$3.8 million, compared to \$1.1 million for the second quarter of 2021. Total gross margin for the second quarter of 2022 was 15.1%, compared to 4.2% in the second quarter of 2021. On a non-GAAP basis, gross margin for the second quarter of 2022 improved to 15.9% from 4.4% in the second quarter of 2021. Product gross profit for the second quarter of 2022 was \$1.9 million, compared to (\$1.4) million of product gross loss in the second quarter of 2021. Product gross margin for the second quarter of 2022 was 9.7%, compared to (7.0)% in the second quarter of 2021. Service and other gross profit for the second quarter of 2022 was \$1.9 million, compared to \$2.5 million of service and other gross profit in the second quarter of 2021. Service and other gross margin for the second quarter of 2022 was 34.6%, compared to 54.5% in the second quarter of 2021.

Operating expenses for the second quarter of 2022 were \$47.5 million, including research and development (R&D) expenses of \$13.5 million, sales and marketing (S&M) expenses of \$23.2 million, and general and administrative (G&A) expenses of \$10.8 million. This compared to operating expenses of \$31.0 million, including R&D expenses of \$8.0 million, S&M expenses of \$13.2 million, and G&A expenses of \$9.7 million in the second quarter of 2021.

Excluding stock-based compensation expense, non-GAAP operating expenses for the second quarter of 2022 were \$40.3 million, including R&D expenses of \$11.7 million, S&M expenses of \$20.3 million, and G&A expenses of \$8.2 million.

Second quarter 2022 net loss was (\$43.8) million, or (\$0.92) per share, compared to net loss of (\$30.2) million, or (\$0.66) per share, for the same period in 2021. On a non-GAAP basis, net loss for the second quarter of 2022 was (\$36.4) million, or (\$0.77) per share, compared to non-GAAP net loss of (\$26.3) million, or (\$0.57) per share for the same period in 2021.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$295.4 million as of June 30, 2022.

Full Year 2022 Financial Guidance

Outset now projects revenue for 2022 of \$105 million to \$110 million, which represents 2% to 7% growth over 2021.

Webcast and Conference Call Details

Outset will host a conference call today, August 1, 2022, at 2:00 p.m. PT / 5:00 p.m. ET to provide a business update and discuss its second quarter 2022 financial results. The dial-in numbers are 877-451-6152 for domestic callers and 201-389-0879 for international callers. The conference ID is 13731999. 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 Tablo devices and its ability to achieve projected cost reductions at the level or within the timeframe estimated; the Company's expectations with respect to anticipated benefits of the TPNIES approval, as well as the Company's expectations regarding the impact of the COVID-19 pandemic and other macroeconomic factors on the Company as well as the impact on 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 Outset's public filings with the Securities and Exchange Commission, including Outset's 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue	\$ 19,621	\$ 20,628	\$ 45,285	\$ 38,838
Service and other revenue	5,436	4,588	10,322	9,294
Total revenue	<u>25,057</u>	<u>25,216</u>	<u>55,607</u>	<u>48,132</u>
Cost of revenue:				
Cost of product revenue ⁽²⁾	17,718	22,077	40,828	42,654
Cost of service and other revenue	3,557	2,087	6,555	4,137
Total cost of revenue	<u>21,275</u>	<u>24,164</u>	<u>47,383</u>	<u>46,791</u>
Gross profit ⁽¹⁾	3,782	1,052	8,224	1,341
Gross margin ⁽¹⁾	15.1 %	4.2 %	14.8 %	2.8 %
Operating expenses:				
Research and development ⁽²⁾	13,521	8,032	24,352	15,602
Sales and marketing ⁽²⁾	23,198	13,204	43,575	26,353
General and administrative ⁽²⁾	10,784	9,722	20,493	18,968
Total operating expenses	<u>47,503</u>	<u>30,958</u>	<u>88,420</u>	<u>60,923</u>
Loss from operations	(43,721)	(29,906)	(80,196)	(59,582)
Other income (expense):				
Interest income and other income, net	459	164	579	276
Interest expense	(481)	(431)	(903)	(853)
Loss before provision for income taxes	(43,743)	(30,173)	(80,520)	(60,159)
Provision for income taxes	96	35	211	74
Net loss	<u>\$ (43,839)</u>	<u>\$ (30,208)</u>	<u>\$ (80,731)</u>	<u>\$ (60,233)</u>
Net loss per share, basic and diluted	<u>\$ (0.92)</u>	<u>\$ (0.66)</u>	<u>\$ (1.69)</u>	<u>\$ (1.36)</u>
Shares used in computing net loss per share, basic and diluted	<u>47,882</u>	<u>45,680</u>	<u>47,686</u>	<u>44,228</u>

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Gross profit				
Product revenue	\$ 1,903	\$ (1,449)	\$ 4,457	\$ (3,816)
Service and other revenue	1,879	2,501	3,767	5,157
Total gross profit	<u>\$ 3,782</u>	<u>\$ 1,052</u>	<u>\$ 8,224</u>	<u>\$ 1,341</u>
Gross margin				
Product revenue	9.7 %	(7.0) %	9.8 %	(9.8) %
Service and other revenue	34.6 %	54.5 %	36.5 %	55.5 %
Total gross margin	15.1 %	4.2 %	14.8 %	2.8 %

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of revenue	\$ 190	\$ 62	\$ 283	\$ 137
Research and development	1,808	643	2,966	1,808
Sales and marketing	2,864	1,052	4,570	2,794
General and administrative	2,552	2,180	4,601	5,050
Total stock-based compensation expense	<u>\$ 7,414</u>	<u>\$ 3,937</u>	<u>\$ 12,420</u>	<u>\$ 9,789</u>

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

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 75,497	\$ 182,348
Short-term investments	186,565	157,140
Accounts receivable, net	24,627	25,600
Inventories	53,689	39,185
Prepaid expenses and other current assets	5,399	5,529
Total current assets	345,777	409,802
Restricted cash	33,311	33,311
Property and equipment, net	15,245	12,964
Operating lease right-of-use assets	6,687	7,231
Other assets	216	156
Total assets	<u>\$ 401,236</u>	<u>\$ 463,464</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,753	\$ 1,763
Accrued compensation and related benefits	15,795	24,948
Accrued expenses and other current liabilities	23,261	13,789
Accrued warranty liability	3,444	3,704
Deferred revenue, current	7,752	6,340
Operating lease liabilities, current	1,235	1,151
Term loan, current	1,000	—
Total current liabilities	55,240	51,695
Accrued interest, noncurrent	960	721
Deferred revenue, noncurrent	205	312
Operating lease liabilities, noncurrent	6,261	6,893
Term loan, noncurrent	28,806	29,762
Total liabilities	91,472	89,383
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, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of June 30, 2022 and December 31, 2021; 47,997 and 47,241 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	48	47
Additional paid-in capital	1,017,396	1,000,212
Accumulated other comprehensive loss	(955)	(184)
Accumulated deficit	(706,725)	(625,994)
Total stockholders' equity	309,764	374,081
Total liabilities and stockholders' equity	<u>\$ 401,236</u>	<u>\$ 463,464</u>

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

	Six Months Ended June 30,	
	2022	2021
Net cash used in operating activities	\$ (76,910)	\$ (69,457)
Net cash used in investing activities	(34,706)	(104,267)
Net cash provided by financing activities	4,765	153,026
Net decrease in cash, cash equivalents and restricted cash	(106,851)	(20,698)
Cash, cash equivalents and restricted cash at beginning of the period	215,659	328,283
Cash, cash equivalents and restricted cash at end of the period ⁽¹⁾	\$ 108,808	\$ 307,585

⁽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,	
	2022	2021
Cash and cash equivalents	\$ 75,497	\$ 274,274
Restricted cash	33,311	33,311
Total cash, cash equivalents and restricted cash *	\$ 108,808	\$ 307,585

* The total cash, including restricted cash, cash equivalents and investment securities as of June 30, 2022 was \$295.4 million; compared to \$429.5 million as of June 30, 2021.

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
GAAP net loss per share, diluted	\$ (0.92)	\$ (0.66)	\$ (1.69)	\$ (1.36)
Stock-based compensation expense	0.15	0.09	0.26	0.22
Non-GAAP net loss per share, diluted	<u>\$ (0.77)</u>	<u>\$ (0.57)</u>	<u>\$ (1.43)</u>	<u>\$ (1.14)</u>

Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
GAAP net loss, diluted	\$ (43,839)	\$ (30,208)	\$ (80,731)	\$ (60,233)
Stock-based compensation expense	7,414	3,937	12,420	9,789
Non-GAAP net loss, diluted	<u>\$ (36,425)</u>	<u>\$ (26,271)</u>	<u>\$ (68,311)</u>	<u>\$ (50,444)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
GAAP gross profit	\$ 3,782	\$ 1,052	\$ 8,224	\$ 1,341
Stock-based compensation expense	190	62	283	137
Non-GAAP gross profit	<u>\$ 3,972</u>	<u>\$ 1,114</u>	<u>\$ 8,507</u>	<u>\$ 1,478</u>
GAAP gross margin	15.1 %	4.2 %	14.8 %	2.8 %
Stock-based compensation expense	0.8	0.2	0.5	0.3
Non-GAAP gross margin	<u>15.9 %</u>	<u>4.4 %</u>	<u>15.3 %</u>	<u>3.1 %</u>
GAAP research and development expense	\$ 13,521	\$ 8,032	\$ 24,352	\$ 15,602
Stock-based compensation expense	(1,808)	(643)	(2,966)	(1,808)
Non-GAAP research and development expense	<u>\$ 11,713</u>	<u>\$ 7,389</u>	<u>\$ 21,386</u>	<u>\$ 13,794</u>
GAAP sales and marketing expense	\$ 23,198	\$ 13,204	\$ 43,575	\$ 26,353
Stock-based compensation expense	(2,864)	(1,052)	(4,570)	(2,794)
Non-GAAP sales and marketing expense	<u>\$ 20,334</u>	<u>\$ 12,152</u>	<u>\$ 39,005</u>	<u>\$ 23,559</u>
GAAP general and administrative expense	\$ 10,784	\$ 9,722	\$ 20,493	\$ 18,968
Stock-based compensation expense	(2,552)	(2,180)	(4,601)	(5,050)
Non-GAAP general and administrative expense	<u>\$ 8,232</u>	<u>\$ 7,542</u>	<u>\$ 15,892</u>	<u>\$ 13,918</u>
GAAP total operating expense	\$ 47,503	\$ 30,958	\$ 88,420	\$ 60,923
Stock-based compensation expense	(7,224)	(3,875)	(12,137)	(9,652)
Non-GAAP total operating expense	<u>\$ 40,279</u>	<u>\$ 27,083</u>	<u>\$ 76,283</u>	<u>\$ 51,271</u>

