

**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 3, 2021**

**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
<b>Common Stock, \$0.001 par value per share</b>	<b>OM</b>	<b>The Nasdaq Stock Market LLC</b>

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 3, 2021, Outset Medical, Inc. (the “**Company**”) issued a press release and will hold its third quarter 2021 earnings conference call announcing the Company’s financial results for the quarter ended September 30, 2021. 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.

<b>Exhibit Number</b>	<b>Description</b>
99.1	<a href="#">Press Release entitled “Outset Medical Reports Third Quarter 2021 Financial Results” dated November 3, 2021</a>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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**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 3, 2021

By: \_\_\_\_\_  
/s/Nabeel Ahmed  
**Nabeel Ahmed**  
**Chief Financial Officer**

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## Outset Medical Reports Third Quarter 2021 Financial Results

*2021 Revenue Guidance Range Elevated to \$99 million to \$101 million*

**San Jose, CA – November 3, 2021** – 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, 2021.

### Recent Highlights

- Recorded net revenue of \$26.3 million in the third quarter of 2021, a 91.3% increase compared to \$13.8 million in the third quarter of 2020
- Achieved gross margin of 11.2% in the third quarter of 2021 compared to (37.3%) in the third quarter of 2020
- Received favorable decision for Tablo under the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) program
- Four clinical abstracts outlining Tablo’s clinical performance in both Home and Acute settings to be shared at the American Society of Nephrology’s Kidney Week Meeting

“Our strong third quarter performance further reinforces our confidence in our business and in our expectations for growth,” said Leslie Trigg, President and Chief Executive Officer. “We are also very pleased to have secured a positive decision on our TPNIES application, which we believe validates Tablo’s value to patients and providers and makes Tablo the first and only technology to receive a TPNIES approval.”

### Third Quarter 2021 Financial Results

Revenue for the third quarter of 2021 was \$26.3 million, representing an increase of 91.3% compared to \$13.8 million in the third quarter of 2020. Product revenue for the third quarter of 2021 was \$21.8 million, representing an increase of 101.9% compared to \$10.8 million in the third quarter of 2020. Service and other revenue for the third quarter of 2021 was \$4.5 million, representing an increase of 52.6% compared to \$2.9 million in the third quarter of 2020.

Total gross profit for the third quarter of 2021 was \$2.9 million, compared to a gross loss of (\$5.1) million for the third quarter of 2020. Total gross margin for the third quarter of 2021 was 11.2%, compared to (37.3%) in the third quarter of 2020. Product gross profit for the third quarter of 2021 was \$1.3 million, compared to (\$6.5) million of product gross loss in the third quarter of 2020. Product gross margin for the third quarter of 2021 was 5.9%, compared to (59.7%) in the third quarter of 2020. Service and other gross profit for the third quarter of 2021 was \$1.6 million, compared to \$1.3 million of service and other gross profit in the third quarter of 2020. Service and other gross margin for the third quarter of 2021 was 36.7%, compared to 45.1% in the third quarter of 2020.

Operating expenses for the third quarter of 2021 were \$33.1 million, including research and development (R&D) expenses of \$9.7 million, sales and marketing (S&M) expenses of \$15.7 million, and general and administrative (G&A) expenses of \$7.6 million. This compared to operating expenses of \$35.6 million, including R&D expenses of \$9.2 million, S&M expenses of \$13.3 million, and G&A expenses of \$13.1 million in the third quarter of 2020.

Excluding stock-based compensation expense, non-GAAP operating expenses for the third quarter of 2021 were \$30.3 million, including R&D expenses of \$9.0 million, S&M expenses of \$14.5 million, and G&A expenses of \$6.8 million.

Third quarter 2021 net loss was (\$30.5) million, or (\$0.65) per share, compared to net loss of (\$42.3) million, or (\$3.44) per share, for the same period in 2020. On a non-GAAP basis, net loss for the third quarter of 2021 was (\$27.6) million, or (\$0.59) per share, compared to non-GAAP net loss of (\$28.4) million, or (\$2.31) per share for the same period in 2020.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$406.4 million as of September 30, 2021.

## **Full Year 2021 Financial Guidance**

Outset projects revenue for the full year 2021 to range from \$99 million to \$101 million, which represents approximately 98% to 102% growth over the Company's fiscal year 2020 revenue. This updated guidance compares to prior 2021 revenue guidance of \$97 million to \$100 million.

## **Webcast and Conference Call Details**

Outset will host a conference call today, November 3, 2021, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its third quarter 2021 financial results. The dial-in numbers are (833) 614-1409 for domestic callers and (914) 987-7130 for international callers. The conference ID is 7975557. 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, profitability and outlook, statements regarding the Company's overall business strategy, plans and objectives of management, the Company's expectations with respect to anticipated benefits of the TPNIES approval, as well as the Company's expectations regarding the continuing impact of the COVID-19 pandemic on the Company and its operations 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

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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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Revenue:</b>				
Product revenue	\$ 21,824	\$ 10,812	\$ 60,662	\$ 26,435
Service and other revenue	4,494	2,944	13,788	6,253
Total revenue	26,318	13,756	74,450	32,688
<b>Cost of revenue:</b>				
Cost of product revenue <sup>(2)</sup>	20,526	17,265	63,180	42,118
Cost of service and other revenue	2,846	1,617	6,983	4,024
Total cost of revenue	23,372	18,882	70,163	46,142
Gross profit <sup>(1)</sup>	2,946	(5,126)	4,287	(13,454)
Gross margin <sup>(1)</sup>	11.2 %	(37.3) %	5.8 %	(41.2) %
<b>Operating expenses:</b>				
Research and development <sup>(2)</sup>	9,729	9,175	25,331	21,066
Sales and marketing <sup>(2)</sup>	15,726	13,344	42,079	29,870
General and administrative <sup>(2)</sup>	7,629	13,088	26,597	21,462
Total operating expenses	33,084	35,607	94,007	72,398
Loss from operations	(30,138)	(40,733)	(89,720)	(85,852)
<b>Other income (expense):</b>				
Interest income and other income, net	99	(3)	375	524
Interest expense	(431)	(428)	(1,284)	(2,461)
Change in fair value of redeemable convertible preferred stock warrant liability	—	437	—	(93)
Loss on extinguishment of term loan	—	(1,567)	—	(1,567)
Loss before provision for income taxes	(30,470)	(42,294)	(90,629)	(89,449)
Provision for income taxes	—	—	74	—
Net loss	\$ (30,470)	\$ (42,294)	\$ (90,703)	\$ (89,449)
<b>Net loss attributable to common stockholders, basic and diluted <sup>(3)</sup></b>				
	\$ (30,470)	\$ (42,294)	\$ (90,703)	\$ (47,281)
<b>Net loss per share attributable to common stockholders, basic and diluted</b>				
	\$ (0.65)	\$ (3.44)	\$ (1.96)	\$ (6.30)
<b>Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted</b>				
	46,588	12,299	46,252	7,508

<sup>(1)</sup> Gross profit and gross margin by source consisted of the following:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>Gross profit</b>				
Product revenue	\$ 1,298	\$ (6,453)	\$ (2,518)	\$ (15,683)
Service and other revenue	1,648	1,327	6,805	2,229
Total gross profit	<u>\$ 2,946</u>	<u>\$ (5,126)</u>	<u>\$ 4,287</u>	<u>\$ (13,454)</u>
<b>Gross margin</b>				
Product revenue	5.9 %	(59.7) %	(4.2) %	(59.3) %
Service and other revenue	36.7 %	45.1 %	49.4 %	35.6 %
Total gross margin	11.2 %	(37.3) %	5.8 %	(41.2) %

<sup>(2)</sup> Include stock-based compensation expenses as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Cost of revenue	\$ 64	\$ 142	\$ 201	\$ 181
Research and development	760	3,074	2,568	3,326
Sales and marketing	1,207	2,645	4,001	2,828
General and administrative	833	8,047	5,883	8,836
Total stock-based compensation expenses	<u>\$ 2,864</u>	<u>\$ 13,908</u>	<u>\$ 12,653</u>	<u>\$ 15,171</u>

<sup>(3)</sup> A reconciliation of the net loss to net loss attributable to common stockholders is as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Net loss	\$ (30,470)	\$ (42,294)	\$ (90,703)	\$ (89,449)
Adjustment to redemption value on redeemable convertible preferred stock	—	—	—	(362)
Deemed dividend on settlement of accrued dividend*	—	—	—	42,530
Net loss attributable to common stockholders, basic and diluted	<u>\$ (30,470)</u>	<u>\$ (42,294)</u>	<u>\$ (90,703)</u>	<u>\$ (47,281)</u>

\* Deemed dividend on settlement of accrued dividend arose as a result of the terms and conditions associated with the Company's redeemable convertible preferred stock outstanding prior to the Company's initial public offering ("IPO"). These terms and conditions were described in the Company's previous SEC filings, including the 424(b) prospectus filed on September 16, 2020 in connection with the IPO.



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

	September 30, 2021 <u>(Unaudited)</u>	December 31, 2020
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 230,508	\$ 294,972
Short-term investments	142,535	19,898
Accounts receivable, net	19,302	6,468
Inventories	34,297	18,384
Prepaid expenses and other current assets	6,659	6,189
Total current assets	<u>433,301</u>	<u>345,911</u>
Restricted cash	33,311	33,311
Property and equipment, net	14,532	14,998
Operating lease right-of-use assets	7,494	8,253
Other assets	166	1,356
Total assets	<u>\$ 488,804</u>	<u>\$ 403,829</u>
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable	\$ 2,702	\$ 4,948
Accrued compensation and related benefits	17,759	16,845
Accrued expenses and other current liabilities	11,389	7,903
Accrued warranty liability	3,234	2,913
Deferred revenue, current	5,212	3,201
Operating lease liabilities, current	1,109	882
Total current liabilities	<u>41,405</u>	<u>36,692</u>
Accrued interest, noncurrent	600	240
Deferred revenue, noncurrent	109	570
Operating lease liabilities, noncurrent	7,199	8,044
Term loan, noncurrent	29,740	29,674
Total liabilities	<u>79,053</u>	<u>75,220</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, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of September 30, 2021 and December 31, 2020; 47,018 and 42,722 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	47	43
Additional paid-in capital	994,486	822,624
Accumulated other comprehensive (loss) income	(20)	1
Accumulated deficit	(584,762)	(494,059)
Total stockholders' equity	<u>409,751</u>	<u>328,609</u>
Total liabilities and stockholders' equity	<u>\$ 488,804</u>	<u>\$ 403,829</u>

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

	<b>Nine Months Ended September 30,</b>	
	<b>2021</b>	<b>2020</b>
Net cash used in operating activities	\$ (97,588)	\$ (73,175)
Net cash used in investing activities	(126,089)	(6,411)
Net cash provided by financing activities	159,213	386,555
Net (decrease) increase in cash, cash equivalents and restricted cash	(64,464)	306,969
Cash, cash equivalents and restricted cash at beginning of the period	328,283	37,669
Cash, cash equivalents and restricted cash at end of the period <sup>(1)</sup>	\$ 263,819	\$ 344,638

<sup>(1)</sup> 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):

	<b>September 30,</b>	
	<b>2021</b>	<b>2020</b>
Cash and cash equivalents	\$ 230,508	\$ 311,327
Restricted cash	33,311	33,311
Total cash, cash equivalents and restricted cash*	\$ 263,819	\$ 344,638

\* The total cash, including restricted cash, cash equivalents and investment securities as of September 30, 2021 was \$406.4 million; compared to \$377.5 million as of September 30, 2020.

**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 attributable to common stockholders:**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
GAAP net loss per share to common stockholders, diluted	\$ (0.65)	\$ (3.44)	\$ (1.96)	\$ (6.30)
Stock-based compensation expense	0.06	1.13	0.27	2.02
Non-GAAP net loss per share to common stockholders, diluted	<u>\$ (0.59)</u>	<u>\$ (2.31)</u>	<u>\$ (1.69)</u>	<u>\$ (4.28)</u>

**Reconciliation between GAAP and non-GAAP net loss attributable to common stockholders:**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
GAAP net loss attributable to common stockholders, diluted	\$ (30,470)	\$ (42,294)	\$ (90,703)	\$ (47,281)
Stock-based compensation expense	2,864	13,908	12,653	15,171
Non-GAAP net loss per share attributable to common stockholders, diluted	<u>\$ (27,606)</u>	<u>\$ (28,386)</u>	<u>\$ (78,050)</u>	<u>\$ (32,110)</u>

**Reconciliation between GAAP and non-GAAP results of operations:**

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
<b>GAAP gross profit</b>	\$ 2,946	\$ (5,126)	\$ 4,287	\$ (13,454)
Stock-based compensation expense	64	142	201	181
Non-GAAP gross profit	<u>\$ 3,010</u>	<u>\$ (4,984)</u>	<u>\$ 4,488</u>	<u>\$ (13,273)</u>
<b>GAAP gross margin</b>	11.2 %	(37.3) %	5.8 %	(41.2) %
Stock-based compensation expense	0.2	1.0	0.3	0.6
Non-GAAP gross margin	<u>11.4 %</u>	<u>(36.3) %</u>	<u>6.1 %</u>	<u>(40.6) %</u>
<b>GAAP research and development expense</b>	\$ 9,729	\$ 9,175	\$ 25,331	\$ 21,066
Stock-based compensation expense	(760)	(3,074)	(2,568)	(3,326)
Non-GAAP research and development expense	<u>\$ 8,969</u>	<u>\$ 6,101</u>	<u>\$ 22,763</u>	<u>\$ 17,740</u>
<b>GAAP sales and marketing expense</b>	\$ 15,726	\$ 13,344	\$ 42,079	\$ 29,870
Stock-based compensation expense	(1,207)	(2,645)	(4,001)	(2,828)
Non-GAAP sales and marketing expense	<u>\$ 14,519</u>	<u>\$ 10,699</u>	<u>\$ 38,078</u>	<u>\$ 27,042</u>
<b>GAAP general and administrative expense</b>	\$ 7,629	\$ 13,088	\$ 26,597	\$ 21,462
Stock-based compensation expense	(833)	(8,047)	(5,883)	(8,836)
Non-GAAP general and administrative expense	<u>\$ 6,796</u>	<u>\$ 5,041</u>	<u>\$ 20,714</u>	<u>\$ 12,626</u>
<b>GAAP total operating expense</b>	\$ 33,084	\$ 35,607	\$ 94,007	\$ 72,398
Stock-based compensation expense	(2,800)	(13,766)	(12,452)	(14,990)
Non-GAAP total operating expense	<u>\$ 30,284</u>	<u>\$ 21,841</u>	<u>\$ 81,555</u>	<u>\$ 57,408</u>

