

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 5, 2021

Outset Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

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

001-39513
(Commission File Number)

20-0514392
(IRS Employer
Identification No.)

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 Results of Operations and Financial Condition.

On May 5, 2021, Outset Medical, Inc. (the “Company”) issued a press release and held its first quarter 2021 earnings conference call announcing the Company’s financial results for the quarter ended March 31, 2021. A copy of the press release is attached hereto as Exhibit 99.1 and incorporated herein by reference.

The information furnished pursuant to Item 2.02 in this Current Report on Form 8-K and the press release attached as 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.

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press Release entitled “Outset Medical Reports First Quarter 2021 Financial Results” dated May 5, 2021

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 5, 2021

By: _____
/s/ Rebecca Chambers
Rebecca Chambers
Chief Financial Officer

Outset Medical Reports First Quarter 2021 Financial Results

San Jose, CA – May 5, 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 first quarter ended March 31, 2021.

Recent Highlights

- Recorded net revenue of \$22.9 million in the first quarter of 2021, a 219% increase compared to \$7.2 million in the first quarter of 2020
- Achieved gross margin of 1.3% for the first quarter of 2021, compared to (49.6%) in the first quarter of 2020
- Appointed global consumer brand builder Andrea Saia to the Board of Directors
- Completed public offering, which included approximately 2.9 million primary shares, raising approximately \$149.7 million in net proceeds to Outset

“Our first quarter was marked by strong revenue performance, continued operational execution, and substantial progress across our strategic initiatives,” said Leslie Trigg, President and Chief Executive Officer. “Demand for Tablo is both increasing and extending beyond the acute and subacute care settings, with a growing number of customers preparing for home care programs. With strong interest in Tablo, a robust backlog and clear visibility on the timing of console placements, we are confident in our positioning for consistent strong performance in 2021 and beyond.”

First Quarter 2021 Financial Results

Revenue for the first quarter of 2021 was \$22.9 million, representing an increase of 219% compared to \$7.2 million in the first quarter of 2020. Product revenue for the first quarter of 2021 was \$18.2 million, representing an increase of 207% compared to \$5.9 million in the first quarter of 2020. Service and other revenue for the first quarter of 2021 was \$4.7 million, representing an increase of 272% compared to \$1.3 million in the first quarter of 2020.

Total gross profit for the first quarter of 2021 was \$0.3 million, compared to a gross loss of (\$3.6) million for the first quarter of 2020. Total gross margin for the first quarter of 2021 was 1.3%, compared to (49.6%) in the first quarter of 2020. Product gross loss for the first quarter of 2021 was (\$2.4) million, compared to (\$3.6) million of product gross loss in the first quarter of 2020. Product gross margin for the first quarter of 2021 was (13.0%), compared to (61.4%) in the first quarter of 2020. Service and other gross profit for the first quarter of 2021 was \$2.7 million, compared to \$0.1 million of service and other gross profit in the first quarter of 2020. Service and other gross margin for the first quarter of 2021 was 56.4%, compared to 5.7% in the first quarter of 2020.

Operating expenses for the first quarter of 2021 were \$30.0 million, including research and development (R&D) expenses of \$7.6 million, sales and marketing (S&M) expenses of \$13.1 million, and general and administrative (G&A) expenses of \$9.2 million. This compared to operating expenses of \$16.6 million, including R&D expenses of \$5.8 million, S&M expenses of \$7.3 million, and G&A expenses of \$3.5 million in the first quarter of 2020.

Excluding stock-based compensation expense, non-GAAP operating expenses for the first quarter of 2021 were \$24.2 million, including R&D expenses of \$6.4 million, S&M expenses of \$11.4 million, and G&A expenses of \$6.4 million.

First quarter 2021 net loss was (\$30.0) million, or (\$0.70) per share, compared to net income of \$4.2 million, or \$0.74 per share, for the same period in 2020. On a non-GAAP basis, net loss for the first quarter of 2021 was (\$24.2) million, or (\$0.56) per share, compared to non-GAAP net income of \$4.7 million, or \$0.84 per share for the same period in 2020.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$310.8 million as of March 31, 2021. Further, the Company generated approximately \$149.7 million in net proceeds from the April 2021 public offering.

Full Year 2021 Financial Guidance

Outset projects revenue for the full year 2021 to range from \$92 million to \$97 million, which represents approximately 84% to 94% growth over the Company’s fiscal year 2020 revenue. This compares to prior 2021 revenue guidance of \$89 million to \$94 million.

Webcast and Conference Call Details

Outset will host a conference call today, May 5, 2021, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its first 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 6787514. 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 flow. 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, 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 424(B)(4) filed on April 12, 2021 in connection with the Company's public offering. 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

Lynn Lewis or Brian Johnston
Gilmartin Group
investors@outsetmedical.com

Media Contact

Nicole Shannon
Director, Marketing Communications for Outset Medical
nshannon@outsetmedical.com

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

	Three Months Ended	
	March 31,	
	2021	2020
Revenue:		
Product revenue	\$ 18,210	\$ 5,926
Service and other revenue	4,706	1,264
Total revenue	22,916	7,190
Cost of revenue:		
Cost of product revenue (2)	20,577	9,562
Cost of service and other revenue	2,050	1,192
Total cost of revenue	22,627	10,754
Gross profit (1)	289	(3,564)
Gross margin (1)	1.3%	(49.6)%
Operating expenses:		
Research and development (2)	7,570	5,838
Sales and marketing (2)	13,149	7,282
General and administrative (2)	9,246	3,526
Total operating expenses	29,965	16,646
Loss from operations	(29,676)	(20,210)
Other income (expense):		
Interest income and other income, net	112	460
Interest expense	(422)	(1,001)
Change in fair value of redeemable convertible preferred stock warrant liability	—	101
Loss before provision for income taxes	(29,986)	(20,650)
Provision for income taxes	39	—
Net loss	\$ (30,025)	\$ (20,650)
Net income (loss) attributable to common stockholders (3):		
Basic	\$ (30,025)	\$ 3,387
Diluted	\$ (30,025)	\$ 4,161
Net income (loss) per share attributable to common stockholders:		
Basic	\$ (0.70)	\$ 0.77
Diluted	\$ (0.70)	\$ 0.74
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:		
Basic	42,760	4,388
Diluted	42,760	5,630

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

	Three Months Ended March 31,	
	2021	2020
Gross profit		
Product	\$ (2,367)	\$ (3,636)
Service and other	2,656	72
Total gross profit	<u>\$ 289</u>	<u>\$ (3,564)</u>
Gross margin		
Product	(13.0) %	(61.4) %
Service and other	56.4 %	5.7 %
Total gross margin	1.3 %	(49.6) %

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

	Three Months Ended March 31,	
	2021	2020
Cost of revenue	\$ 75	\$ 19
Research and development	1,165	118
Sales and marketing	1,742	82
General and administrative	2,870	361
Total stock-based compensation expenses	<u>\$ 5,852</u>	<u>\$ 580</u>

(3) A reconciliation of the net loss to net income (loss) attributable to common stockholders is as follows:

	Three Months Ended March 31,	
	2021	2020
Net loss	\$ (30,025)	\$ (20,650)
Adjustment to redemption value on redeemable convertible preferred stock	—	(362)
Deemed dividend on settlement of accrued dividend ⁽⁴⁾	—	42,530
Undistributed earnings allocated to participating securities ⁽⁴⁾	—	(18,131)
Net income (loss) attributable to common stockholders, basic	\$ (30,025)	\$ 3,387
Undistributed earnings reallocated to dilutive potential common shares	—	774
Net income (loss) attributable to common stockholders, diluted	<u>\$ (30,025)</u>	<u>\$ 4,161</u>

(4) Deemed dividend on settlement of accrued dividend and undistributed earnings allocated to participating securities arose as a result of the terms and conditions associated with the Company's redeemable convertible preferred stock outstanding as of March 31, 2020. 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 Company's initial public offering.

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

	March 31, 2021	December 31, 2020
	<u>(Unaudited)</u>	
Assets		
Current assets:		
Cash and cash equivalents	\$ 251,767	\$ 294,972
Short-term investments	25,717	19,898
Accounts receivable, net	12,110	6,468
Inventories	24,554	18,384
Prepaid expenses and other current assets	7,578	6,189
Total current assets	321,726	345,911
Restricted cash	33,311	33,311
Property and equipment, net	15,548	14,998
Operating lease right-of-use assets	8,004	8,253
Other assets	1,240	1,356
Total assets	\$ 379,829	\$ 403,829
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,651	\$ 4,948
Accrued compensation and related benefits	12,602	16,845
Accrued expenses and other current liabilities	8,183	7,903
Accrued warranty liability	2,860	2,913
Deferred revenue, current	3,540	3,201
Operating lease liabilities, current	984	882
Total current liabilities	34,820	36,692
Accrued interest, noncurrent	359	240
Deferred revenue, noncurrent	536	570
Operating lease liabilities, noncurrent	7,773	8,044
Term loan, noncurrent	29,696	29,674
Total liabilities	73,184	75,220
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, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of March 31, 2021 and December 31, 2020; 42,888 and 42,722 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	43	43
Additional paid-in capital	830,694	822,624
Accumulated other comprehensive (loss) income	(8)	1
Accumulated deficit	(524,084)	(494,059)
Total stockholders' equity	306,645	328,609
Total liabilities and stockholders' equity	\$ 379,829	\$ 403,829

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

	Three Months Ended March 31,	
	2021	2020
Net cash used in operating activities	\$ (38,616)	\$ (24,893)
Net cash (used in) provided by investing activities	(6,807)	19,159
Net cash provided by financing activities	2,218	126,770
Net (decrease) increase in cash, cash equivalents and restricted cash	(43,205)	121,036
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 ⁽¹⁾	\$ 285,078	\$ 158,705

⁽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,	
	2021	2019
Cash and cash equivalents	\$ 251,767	\$ 157,962
Restricted cash	33,311	743
Total cash, cash equivalents and restricted cash ⁽²⁾	\$ 285,078	\$ 158,705

⁽²⁾ The total cash, including restricted cash, cash equivalents and short-term investments as of March 31, 2021 was \$310.8 million; compared to \$169.8 million as of March 31, 2020.

Outset Medical, Inc.
Results of Operations – Non-GAAP
(in thousands, except per share amounts)
(unaudited)

Reconciliation between GAAP and non-GAAP net income (loss) per share attributable to common stockholders:

	2021
GAAP net income (loss) per share to common stockholders, diluted	\$ (0.70)
Stock-based compensation expense	\$ 0.14
Non-GAAP net income (loss) per share to common stockholders, diluted	\$ (0.56)

Reconciliation between GAAP and non-GAAP net income (loss) attributable to common stockholders:

	2021
GAAP net income (loss) attributable to common stockholders, diluted	\$ (30,025)
Stock-based compensation expense	5,852
Non-GAAP net income (loss) per share attributable to common stockholders, diluted	\$ (24,173)

Reconciliation between GAAP and non-GAAP results of operations:

	2021
GAAP gross profit	\$ 289
Stock-based compensation expense	75
Non-GAAP gross profit	\$ 364
GAAP gross margin	1.3%
Stock-based compensation expense	0.3
Non-GAAP gross margin	1.6%
GAAP research and development expense	\$ 7,570
Stock-based compensation expense	(1,165)
Non-GAAP research and development expense	\$ 6,405
GAAP sales and marketing expense	\$ 13,149
Stock-based compensation expense	(1,742)
Non-GAAP sales and marketing expense	\$ 11,407
GAAP general and administrative expense	\$ 9,246
Stock-based compensation expense	(2,870)
Non-GAAP general and administrative expense	\$ 6,376
GAAP total operating expense	\$ 29,965
Stock-based compensation expense	(5,777)
Non-GAAP total operating expense	\$ 24,188