



Outset Medical Reports Fourth Quarter and Full Year 2020 Financial Results

March 9, 2021

SAN JOSE, Calif.--(BUSINESS WIRE)--Mar. 9, 2021-- Outset Medical, Inc. (Nasdaq: OM) ("Outset"), 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 fourth quarter and full year ended December 31, 2020.

Recent Highlights

- Recorded net revenue of \$17.2 million in the fourth quarter and \$49.9 million for the full year of 2020, representing 143% and 231% increases respectively, over the corresponding periods of 2019
- Achieved GAAP gross margin of 2.4% for the fourth quarter of 2020, compared to (39.2%) in the fourth quarter of 2019
- Manufactured the first Tablo consoles at Outset's facility in Tijuana, Mexico during the first quarter 2021
- Appointed health care industry veteran and digital health expert Karen Drexler to the Board of Directors

"In the fourth quarter our team continued to outperform while building a solid foundation for growth through 2021 and beyond," said Leslie Trigg, President and Chief Executive Officer. "We expanded our customer base, deepened our relationships with top health systems, and continued to deliver an exceptional Tablo home experience for patients and their caregivers. More recently, we manufactured the first Tablo consoles at our new facility in Mexico, one quarter ahead of schedule, marking a milestone achievement for a key strategic initiative."

Fourth Quarter 2020 Financial Results

Revenue for the fourth quarter of 2020 was \$17.2 million, representing an increase of 143% compared to \$7.1 million in the fourth quarter of 2019. Product revenue for the fourth quarter of 2020 was \$13.2 million, representing an increase of 111% compared to \$6.2 million in the fourth quarter of 2019. Service and other revenue for the fourth quarter of 2020 was \$4.1 million, representing an increase of 387% compared to \$0.8 million in the fourth quarter of 2019.

Total gross profit for the fourth quarter of 2020 was \$0.4 million, compared to a gross loss of (\$2.8) million for the fourth quarter of 2019. Total gross margin for the fourth quarter of 2020 was 2.4%, compared to (39.2%) in the fourth quarter of 2019. Product gross loss for the fourth quarter of 2020 was (\$1.7) million, compared to (\$2.0) million of product gross loss in the fourth quarter of 2019. Product gross margin for the fourth quarter of 2020 was (13.2%), compared to (31.4%) in the fourth quarter of 2019. Service and other gross profit for the fourth quarter of 2020 was \$2.2 million, compared to (\$0.8) million of service and other gross loss in the fourth quarter of 2019. Service and other gross margin for the fourth quarter of 2020 was 53.0%, compared to (97.5%) in the fourth quarter of 2019.

Operating expenses for the fourth quarter of 2020 were \$32.0 million, including research and development (R&D) expenses of \$7.8 million, sales and marketing (S&M) expenses of \$15.2 million, and general and administrative (G&A) expenses of \$9.1 million. This compared to operating expenses of \$15.8 million, including R&D expenses of \$6.6 million, S&M expenses of \$6.9 million, and G&A expenses of \$2.3 million in the fourth quarter of 2019.

Excluding stock-based compensation expense, non-GAAP operating expenses for the fourth quarter of 2020 were \$25.8 million, including R&D expenses of \$6.5 million, S&M expenses of \$13.6 million, and G&A expenses of \$5.7 million.

Fourth quarter 2020 net loss was (\$32.0) million, or (\$0.75) per share, compared to a net loss of (\$19.4) million, or (\$21.18) per share, for the same period in 2019. On a non-GAAP basis, net loss for the fourth quarter of 2020 was (\$25.8) million, or (\$0.60) per share, compared to a non-GAAP net loss of (\$19.2) million, or (\$20.91) per share for the same period in 2019.

Full Year 2020 Financial Results

Revenue for the full year of 2020 was \$49.9 million, representing an increase of 231% compared to \$15.1 million for 2019. Product revenue for the full year of 2020 was \$39.6 million, representing an increase of 188% compared to \$13.8 million for 2019. Service and other revenue for the full year of 2020 was \$10.3 million, representing an increase of 677% compared to \$1.3 million for 2019.

Total gross loss for the full year of 2020 was (\$13.0) million, compared to a gross loss of (\$17.8) million for 2019. Total gross margin for the full year of 2020 was (26.1%), compared to (118.1%) in 2019. Product gross loss for the full year of 2020 was (\$17.4) million, compared to (\$13.4) million of product gross loss in 2019. Product gross margin for the full year of 2020 was (44.0%), compared to (97.6%) in 2019. Service and other gross profit for the full year of 2020 was \$4.4 million, compared to (\$4.4) million of service and other gross loss in 2019. Service and other gross margin for the full year of 2020 was 42.5%, compared to (330.4%) in 2019.

Operating expenses for the full year of 2020 were \$104.4 million, including R&D expenses of \$28.9 million, S&M expenses of \$45.1 million, and G&A expenses of \$30.5 million. This compared to operating expenses of \$52.5 million, including R&D expenses of \$23.3 million, S&M expenses of \$20.3 million, and G&A expenses of \$8.9 million for 2019.

Excluding stock-based compensation expense, non-GAAP operating expenses for the full year of 2020 were \$83.2 million, including R&D expenses of \$24.2 million, S&M expenses of \$40.6 million, and G&A expenses of \$18.4 million.

Full year 2020 net loss attributable to common stockholders was (\$79.3) million, or (\$4.85) per share, compared to a net loss attributable to common stockholders of (\$85.5) million, or (\$99.58) per share, for 2019. On a non-GAAP basis, net loss for the full year of 2020 was (\$57.9) million, or (\$3.54) per share, compared to a non-GAAP net loss of (\$84.6) million, or (\$98.55) per share for 2019.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$348.2 million as of December 31, 2020, compared to \$70.8 million as of December 31, 2019.

Full Year 2021 Financial Guidance

Outset projects revenue for the full year 2021 to range from \$89 million to \$94 million, which represents approximately 78 to 88% growth over the company's fiscal year 2020 revenue.

First Quarter 2021 Financial Guidance

Outset projects revenue for the first quarter 2021 to range from \$21 million to \$22 million, which represents approximately 192 to 206% growth over the company's first quarter 2020 revenue.

Webcast and Conference Call Details

Outset will host a conference call today, March 9, 2021, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its fourth quarter and full year 2020 financial results. The dial-in numbers are (833) 614-1409 for domestic callers and (914) 987-7130 for international callers. The conference ID is 8495745. 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 December 3, 2020 in connection with the company's secondary 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.

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

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2020	2019	2020	2019
Revenue:				
Product revenue	\$ 13,177	\$ 6,249	\$ 39,612	\$ 13,750
Service and other revenue	4,070	836	10,323	1,328
Total revenue	17,247	7,085	49,935	15,078

Cost of revenue:				
Cost of product revenue ⁽¹⁾	14,917	8,214	57,035	27,164
Cost of service and other revenue	<u>1,913</u>	<u>1,651</u>	<u>5,937</u>	<u>5,716</u>
Total cost of revenue	<u>16,830</u>	<u>9,865</u>	<u>62,972</u>	<u>32,880</u>
Gross profit	417	(2,780)	(13,037)	(17,802)
Gross margin	2.4 %	(39.2) %	(26.1) %	(118.1) %
Operating expenses:				
Research and development ⁽¹⁾	7,784	6,629	28,850	23,327
Sales and marketing ⁽¹⁾	15,198	6,883	45,068	20,259
General and administrative ⁽¹⁾	<u>9,050</u>	<u>2,278</u>	<u>30,512</u>	<u>8,919</u>
Total operating expenses	<u>32,032</u>	<u>15,790</u>	<u>104,430</u>	<u>52,505</u>
Loss from operations	(31,615)	(18,570)	(117,467)	(70,307)
Other income (expense):				
Interest income and other income, net	2	374	526	2,485
Interest expense	(430)	(1,020)	(2,891)	(4,257)
Change in fair value of redeemable convertible preferred stock warrant liability	—	(230)	(93)	3,800
Loss on extinguishment of term loan	<u>—</u>	<u>—</u>	<u>(1,567)</u>	<u>—</u>
Loss before provision for income taxes	(32,043)	(19,446)	(121,492)	(68,279)
Provision for income taxes	<u>—</u>	<u>—</u>	<u>—</u>	<u>20</u>
Net loss	<u>\$ (32,043)</u>	<u>\$ (19,446)</u>	<u>\$ (121,492)</u>	<u>\$ (68,299)</u>
Net loss attributable to common stockholders, basic and diluted	<u>\$ (32,043)</u>	<u>\$ (19,446)</u>	<u>\$ (79,324)</u>	<u>\$ (85,461)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.75)</u>	<u>\$ (21.18)</u>	<u>\$ (4.85)</u>	<u>\$ (99.58)</u>
Weighted average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>42,715</u>	<u>918</u>	<u>16,358</u>	<u>858</u>

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

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2020	2019	2020	2019
Cost of revenue	\$ 74	\$ 2	\$ 255	\$ 5
Research and development	1,289	62	4,615	328
Sales and marketing	1,595	53	4,423	172
General and administrative	<u>3,310</u>	<u>130</u>	<u>12,146</u>	<u>378</u>
Total stock-based compensation expenses	<u>\$ 6,268</u>	<u>\$ 247</u>	<u>\$ 21,439</u>	<u>\$ 883</u>

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

	December 31,	
	2020	2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 294,972	\$ 36,926
Short-term investments	19,898	33,152
Accounts receivable, net	6,468	3,914
Inventories	18,384	4,596
Prepaid expenses and other current assets	<u>6,189</u>	<u>1,058</u>
Total current assets	345,911	79,646
Restricted cash	33,311	743
Property and equipment, net	14,998	7,895
Operating lease right-of-use assets	8,253	—
Other assets	<u>1,356</u>	<u>82</u>
Total assets	<u>\$ 403,829</u>	<u>\$ 88,366</u>
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 4,948	\$ 4,960
Accrued compensation and related benefits	16,845	6,956

Accrued expenses and other current liabilities	7,903	2,909
Accrued warranty liability	2,913	1,702
Deferred revenue, current	3,201	883
Operating lease liabilities, current	882	—
Term loan, current	—	7,500
Total current liabilities	36,692	24,910
Accrued interest, noncurrent	240	217
Deferred revenue, noncurrent	570	134
Operating lease liabilities, noncurrent	8,044	—
Redeemable convertible preferred stock warrant liability	—	4,285
Term loan, noncurrent	29,674	21,561
Total liabilities	75,220	51,107
Commitments and contingencies		
Redeemable convertible preferred stock, \$0.001 par value; no shares authorized and no shares issued and outstanding as of December 31, 2020; 154,592 shares authorized and 147,214 shares issued and outstanding as of December 31, 2019	—	409,446
Stockholders' equity (deficit):		
Preferred stock, \$0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, \$0.001 par value; 300,000 and 240,000 shares authorized as of December 31, 2020 and 2019, respectively; 42,722 and 922 shares issued and outstanding as of December 31, 2020 and 2019, respectively	43	1
Additional paid-in capital	822,624	357
Accumulated other comprehensive income	1	22
Accumulated deficit	(494,059)	(372,567)
Total stockholders' equity (deficit)	328,609	(372,187)
Total liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)	\$ 403,829	\$ 88,366

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

	Years Ended December 31,	
	2020	2019
Net cash used in operating activities	\$ (99,015)	\$ (70,292)
Net cash provided by investing activities	3,947	74,297
Net cash provided by financing activities	385,682	249
Net increase in cash, cash equivalents and restricted cash	290,614	4,254
Cash, cash equivalents and restricted cash at beginning of the period	37,669	33,415
Cash, cash equivalents and restricted cash at end of the period ⁽¹⁾	\$ 328,283	\$ 37,669

(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):

	December 31,	
	2020	2019
Cash and cash equivalents	\$ 294,972	\$ 36,926
Restricted cash	33,311	743
Total cash, cash equivalents and restricted cash*	\$ 328,283	\$ 37,669

* The total cash, including restricted cash, cash equivalents and short-term investments as of December 31, 2020 was \$348.2 million; compared to \$70.8 million as of December 31, 2019.

Appendix A

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

	December 31,		Years Ended December 31,	
	2020	2019	2020	2019
	GAAP net loss per share to common stockholders, diluted	\$ (0.75)	\$ (21.18)	\$ (4.85)
Stock-based compensation expense	0.15	\$ 0.27	1.31	1.03
Non-GAAP net loss per share to common stockholders, diluted	<u>\$ (0.60)</u>	<u>\$ (20.91)</u>	<u>\$ (3.54)</u>	<u>\$ (98.55)</u>

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

	Three Months Ended		Years Ended December 31,	
	December 31,		2020	2019
	2020	2019	2020	2019
GAAP net loss attributable to common stockholders, diluted	\$ (32,043)	\$ (19,446)	\$ (79,324)	\$ (85,461)
Stock-based compensation expense	6,268	247	21,439	883
Non-GAAP net loss per share attributable to common stockholders, diluted	<u>\$ (25,775)</u>	<u>\$ (19,199)</u>	<u>\$ (57,885)</u>	<u>\$ (84,578)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended		Years Ended December 31,	
	December 31,		2020	2019
	2020	2019	2020	2019
GAAP gross profit	\$ 417	\$ (2,780)	\$ (13,037)	\$ (17,802)
Stock-based compensation expense	74	2	255	5
Non-GAAP gross profit	<u>\$ 491</u>	<u>\$ (2,778)</u>	<u>\$ (12,782)</u>	<u>\$ (17,797)</u>
GAAP gross margin	2.4 %	(39.2) %	(26.1) %	(118.1) %
Stock-based compensation expense	0.4	—	0.5	—
Non-GAAP gross margin	<u>2.8 %</u>	<u>(39.2) %</u>	<u>(25.6) %</u>	<u>(118.1) %</u>
GAAP research and development expense	\$ 7,784	\$ 6,629	\$ 28,850	\$ 23,327
Stock-based compensation expense	(1,289)	(62)	(4,615)	(328)
Non-GAAP research and development expense	<u>\$ 6,495</u>	<u>\$ 6,567</u>	<u>\$ 24,235</u>	<u>\$ 22,999</u>
GAAP sales and marketing expense	\$ 15,198	\$ 6,883	\$ 45,068	\$ 20,259
Stock-based compensation expense	(1,595)	(53)	(4,423)	(172)
Non-GAAP sales and marketing expense	<u>\$ 13,603</u>	<u>\$ 6,830</u>	<u>\$ 40,645</u>	<u>\$ 20,087</u>
GAAP general and administrative expense	\$ 9,050	\$ 2,278	\$ 30,512	\$ 8,919
Stock-based compensation expense	(3,310)	(130)	(12,146)	(378)
Non-GAAP general and administrative expense	<u>\$ 5,740</u>	<u>\$ 2,148</u>	<u>\$ 18,366</u>	<u>\$ 8,541</u>
GAAP total operating expense	\$ 32,032	\$ 15,790	\$ 104,430	\$ 52,505
Stock-based compensation expense	(6,194)	(245)	(21,184)	(878)
Non-GAAP total operating expense	<u>\$ 25,838</u>	<u>\$ 15,545</u>	<u>\$ 83,246</u>	<u>\$ 51,627</u>

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Source: Outset Medical, Inc.