



Outset Medical Reports Fourth Quarter and Full Year 2021 Financial Results

February 16, 2022

Record Annual Revenue of \$102.6 Million; 105% Year-over-Year Growth

SAN JOSE, Calif.--(BUSINESS WIRE)--Feb. 16, 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 reported financial results for the fourth quarter and full year ended December 31, 2021. The Company also announced that Leslie Trigg has been appointed Chair of the Board of Directors in addition to her ongoing role as President and Chief Executive Officer.

Recent Highlights

- Recorded net revenue of \$28.2 million in the fourth quarter of 2021, a 63.2% increase compared to \$17.2 million in the fourth quarter of 2020, and \$102.6 million for the full year of 2021, representing an increase of 105.5% compared to \$49.9 million for 2020
- Achieved gross margin for the fourth quarter of 2021 of 11.8%, compared to 2.4% in the fourth quarter of 2020
- Signed agreements with 7 of the 8 largest national health systems and one-third of the largest 100 regional health systems
- Granted 510(k) clearance from the Food and Drug Administration (FDA) for Tablo® Hemodialysis System cartridge, enabling full production in Mexico
- Received the first-ever approval for the Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES) program from the Centers for Medicare & Medicaid Services (CMS), which deemed Tablo® a substantial clinical improvement over the incumbent home hemodialysis device
- Released its inaugural Environmental, Social, and Governance (ESG) report highlighting the Company's ESG-related programs, priorities, goals, and performance
- Leslie Trigg appointed Chair in addition to her ongoing role as Chief Executive Officer. Former Chairman D. Keith Grossman continues to serve on the board and has been appointed Lead Independent Director

"Our entire team contributed to an exceptional 2021, driving record revenue growth, meaningful progress toward our long-term gross margin goal and excellent visibility into 2022," said Leslie Trigg, Chair and Chief Executive Officer. "Our established relationships with 7 of the 8 largest national health systems and one-third of the largest 100 regional health systems puts us in a strong position for growth this year in both the acute and home settings."

"On behalf of the Outset Board of Directors, I am pleased to announce Leslie's appointment to the additional role of Board Chair," said D. Keith Grossman, Lead Independent Director. "We look forward to continuing to support Leslie and the entire team as Outset continues to transform the dialysis industry."

Fourth Quarter 2021 Financial Results

Revenue for the fourth quarter of 2021 was \$28.2 million, representing an increase of 63.2% compared to \$17.2 million in the fourth quarter of 2020. Product revenue for the fourth quarter of 2021 was \$23.7 million, representing an increase of 79.5% compared to \$13.2 million in the fourth quarter of 2020. Service and other revenue for the fourth quarter of 2021 was \$4.5 million, representing an increase of 10.6% compared to \$4.1 million in the fourth quarter of 2020.

Total gross profit for the fourth quarter of 2021 was \$3.3 million, compared to a gross loss of \$0.4 million for the fourth quarter of 2020. Total gross margin for the fourth quarter of 2021 was 11.8%, compared to 2.4% in the fourth quarter of 2020. On a non-GAAP basis, gross margin for the fourth quarter of 2021 improved to 12% from 2.8% in the fourth quarter of 2020. Product gross profit for the fourth quarter of 2021 was \$2.2 million, compared to (\$1.7) million of product gross loss in the fourth quarter of 2020. Product gross margin for the fourth quarter of 2021 was 9.3%, compared to (13.2)% in the fourth quarter of 2020. Service and other gross profit for the fourth quarter of 2021 was \$1.1 million, compared to \$2.2 million of service and other gross profit in the fourth quarter of 2020. Service and other gross margin for the fourth quarter of 2021 was 25.1%, compared to 53.0% in the fourth quarter of 2020.

Operating expenses for the fourth quarter of 2021 were \$44.1 million, including research and development (R&D) expenses of \$11.4 million, sales and marketing (S&M) expenses of \$23.0 million, and general and administrative (G&A) expenses of \$9.7 million. This compared to operating expenses of \$32.0 million, including R&D expenses of \$7.8 million, S&M expenses of \$15.2 million, and G&A expenses of \$9.1 million in the fourth quarter of 2020.

Excluding stock-based compensation expense, non-GAAP operating expenses for the fourth quarter of 2021 were \$39.4 million, including R&D expenses of \$10.2 million, S&M expenses of \$21.1 million, and G&A expenses of \$8.1 million.

Fourth quarter 2021 net loss was (\$41.2) million, or (\$0.87) per share, compared to net loss of (\$32.0) million, or (\$0.75) per share, for the same period in 2020. On a non-GAAP basis, net loss for the fourth quarter of 2021 was (\$36.4) million, or (\$0.77) per share, compared to non-GAAP net loss of (\$25.8) million, or (\$0.60) per share for the same period in 2020.

Full Year 2021 Financial Results

Revenue for the full year of 2021 was \$102.6 million, representing an increase of 105.5% compared to \$49.9 million for 2020. Product revenue for the full year of 2021 was \$84.3 million, representing an increase of 112.8% compared to \$39.6 million for 2020. Service and other revenue for the full year of 2021 was \$18.3 million, representing an increase of 77.2% compared to \$10.3 million for 2020.

Total gross profit for the full year of 2021 was \$7.6 million, compared to a gross loss of (\$13.0) million for 2020. Total gross margin for the full year of 2021 was 7.4%, compared to (26.1)% in 2020. Product gross loss for the full year of 2021 was (\$0.3) million, compared to (\$17.4) million of product gross loss in 2020. Product gross margin for the full year of 2021 was (0.4)%, compared to (44.0)% in 2020. Service and other gross profit for the full year of 2021 was \$7.9 million, compared to \$4.4 million of service and other gross profit in 2020. Service and other gross margin for the full year of 2021 was 43.4%, compared to 42.5% in 2020.

Operating expenses for the full year of 2021 were \$138.1 million, including R&D expenses of \$36.7 million, S&M expenses of \$65.1 million, and G&A expenses of \$36.3 million. This compared to operating expenses of \$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 for 2020.

Excluding stock-based compensation expense, non-GAAP operating expenses for the full year of 2021 were \$121.0 million, including R&D expenses of \$32.9 million, S&M expenses of \$59.2 million, and G&A expenses of \$28.8 million.

Full year 2021 net loss attributable to common stockholders was (\$131.9) million, or (\$2.89) per share, compared to a net loss attributable to common stockholders of (\$79.3) million, or (\$4.85) per share, for 2020. On a non-GAAP basis, net loss for the full year of 2021 was (\$114.5) million, or (\$2.51) per share, compared to a non-GAAP net loss of (\$57.9) million, or (\$3.54) per share for 2020.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$372.8 million as of December 31, 2021.

Full Year 2022 Financial Guidance

Outset projects revenue for the full year 2022 to range from \$142 million to \$150 million, which represents approximately 38% to 46% growth over the Company's fiscal year 2021 revenue.

Webcast and Conference Call Details

Outset will host a conference call today, February 16, 2022, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its fourth quarter and full year 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 6892802. 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 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 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.

Condensed Statements of Operations
(in thousands, except per share amounts)
(unaudited)

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Revenue:				
Product revenue	\$ 23,650	\$ 13,177	\$ 84,312	\$ 39,612
Service and other revenue	4,502	4,070	18,290	10,323
Total revenue	<u>28,152</u>	<u>17,247</u>	<u>102,602</u>	<u>49,935</u>
Cost of revenue:				
Cost of product revenue ⁽²⁾	21,459	14,917	84,639	57,035
Cost of service and other revenue	3,372	1,913	10,355	5,937
Total cost of revenue	<u>24,831</u>	<u>16,830</u>	<u>94,994</u>	<u>62,972</u>
Gross profit ⁽¹⁾	3,321	417	7,608	(13,037)
Gross margin ⁽¹⁾	11.8 %	2.4 %	7.4 %	(26.1) %
Operating expenses:				
Research and development ⁽²⁾	11,410	7,784	36,741	28,850
Sales and marketing ⁽²⁾	22,991	15,198	65,070	45,068
General and administrative ⁽²⁾	9,719	9,050	36,316	30,512
Total operating expenses	<u>44,120</u>	<u>32,032</u>	<u>138,127</u>	<u>104,430</u>
Loss from operations	(40,799)	(31,615)	(130,519)	(117,467)
Other income (expense):				
Interest income and other income, net	123	2	498	526
Interest expense	(431)	(430)	(1,715)	(2,891)
Change in fair value of redeemable convertible preferred stock warrant liability	—	—	—	(93)
Loss on extinguishment of term loan	—	—	—	(1,567)
Loss before provision for income taxes	(41,107)	(32,043)	(131,736)	(121,492)
Provision for income taxes	125	—	199	—
Net loss	<u>\$ (41,232)</u>	<u>\$ (32,043)</u>	<u>\$ (131,935)</u>	<u>\$ (121,492)</u>
Net loss attributable to common stockholders, basic and diluted ⁽³⁾	<u>\$ (41,232)</u>	<u>\$ (32,043)</u>	<u>\$ (131,935)</u>	<u>\$ (79,324)</u>
Net loss per share attributable to common stockholders, basic and diluted	<u>\$ (0.87)</u>	<u>\$ (0.75)</u>	<u>\$ (2.89)</u>	<u>\$ (4.85)</u>
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	<u>47,169</u>	<u>42,715</u>	<u>45,589</u>	<u>16,358</u>

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

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
Gross profit				
Product revenue	\$ 2,191	\$ (1,740)	\$ (327)	\$ (17,423)
Service and other revenue	1,130	2,157	7,935	4,386
Total gross profit	<u>\$ 3,321</u>	<u>\$ 417</u>	<u>\$ 7,608</u>	<u>\$ (13,037)</u>
Gross margin				
Product revenue	9.3 %	(13.2) %	(0.4) %	(44.0) %
Service and other revenue	25.1 %	53.0 %	43.4 %	42.5 %
Total gross margin	11.8 %	2.4 %	7.4 %	(26.1) %

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

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2021	2020	2021	2020

Cost of revenue	\$ 68	\$ 74	\$ 269	\$ 255
Research and development	1,241	1,289	3,809	4,615
Sales and marketing	1,896	1,595	5,897	4,423
General and administrative	1,587	3,310	7,470	12,146
Total stock-based compensation expenses	<u>\$ 4,792</u>	<u>\$ 6,268</u>	<u>\$ 17,445</u>	<u>\$ 21,439</u>

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

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
Net loss	\$ (41,232)	\$ (32,043)	\$ (131,935)	\$ (121,492)
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>\$ (41,232)</u>	<u>\$ (32,043)</u>	<u>\$ (131,935)</u>	<u>\$ (79,324)</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)

	December 31, 2021	December 31, 2020
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 182,348	\$ 294,972
Short-term investments	157,140	19,898
Accounts receivable, net	25,600	6,468
Inventories	39,185	18,384
Prepaid expenses and other current assets	5,529	6,189
Total current assets	<u>409,802</u>	<u>345,911</u>
Restricted cash	33,311	33,311
Property and equipment, net	12,964	14,998
Operating lease right-of-use assets	7,231	8,253
Other assets	156	1,356
Total assets	<u>\$ 463,464</u>	<u>\$ 403,829</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,763	\$ 4,948
Accrued compensation and related benefits	24,948	16,845
Accrued expenses and other current liabilities	13,789	7,903
Accrued warranty liability	3,704	2,913
Deferred revenue, current	6,340	3,201
Operating lease liabilities, current	1,151	882
Total current liabilities	<u>51,695</u>	<u>36,692</u>
Accrued interest, noncurrent	721	240
Deferred revenue, noncurrent	312	570
Operating lease liabilities, noncurrent	6,893	8,044
Term loan, noncurrent	29,762	29,674
Total liabilities	<u>89,383</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 December 31, 2021 and 2020	—	—

Common stock, \$0.001 par value; 300,000 shares authorized as of December 31, 2021 and 2020; 47,241 and 42,722 shares issued and outstanding as of December 31, 2021 and 2020, respectively

	47	43
Additional paid-in capital	1,000,212	822,624
Accumulated other comprehensive (loss) income	(184)	1
Accumulated deficit	<u>(625,994)</u>	<u>(494,059)</u>
Total stockholders' equity	<u>374,081</u>	<u>328,609</u>
Total liabilities and stockholders' equity	<u>\$ 463,464</u>	<u>\$ 403,829</u>

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

	Years Ended December 31,	
	2021	2020
Net cash used in operating activities	\$ (130,264)	\$ (99,015)
Net cash provided by (used in) investing activities	(142,507)	3,947
Net cash provided by financing activities	160,147	385,682
Net (decrease) increase in cash, cash equivalents and restricted cash	<u>(112,624)</u>	<u>290,614</u>
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⁾	<u>\$ 215,659</u>	<u>\$ 328,283</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):

	December 31,	
	2021	2020
Cash and cash equivalents	\$ 182,348	\$ 294,972
Restricted cash	33,311	33,311
Total cash, cash equivalents and restricted cash*	<u>\$ 215,659</u>	<u>\$ 328,283</u>

* The total cash, including restricted cash, cash equivalents and investment securities as of December 31, 2021 was \$372.8 million; compared to \$348.2 million as of December 31, 2020.

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		Years Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
GAAP net loss per share to common stockholders, diluted	\$ (0.87)	\$ (0.75)	\$ (2.89)	\$ (4.85)
Stock-based compensation expense	0.10	0.15	0.38	1.31
Non-GAAP net loss per share to common stockholders, diluted	<u>\$ (0.77)</u>	<u>\$ (0.60)</u>	<u>\$ (2.51)</u>	<u>\$ (3.54)</u>

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

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2021	2020	2021	2020
GAAP net loss attributable to common stockholders, diluted	\$ (41,232)	\$ (32,043)	\$ (131,935)	\$ (79,324)
Stock-based compensation expense	4,792	6,268	17,445	21,439

Non-GAAP net loss per share attributable to common stockholders, diluted	\$ (36,440)	\$ (25,775)	\$ (114,490)	\$ (57,885)
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Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended December 31,		Years Ended December 31,	
	2021	2020	2021	2020
GAAP gross profit	\$ 3,321	\$ 417	\$ 7,608	\$ (13,037)
Stock-based compensation expense	68	74	269	255
Non-GAAP gross profit	<u>\$ 3,389</u>	<u>\$ 491</u>	<u>\$ 7,877</u>	<u>\$ (12,782)</u>
GAAP gross margin	11.8 %	2.4 %	7.4 %	(26.1)%
Stock-based compensation expense	0.2	0.4	0.3	0.5
Non-GAAP gross margin	<u>12.0 %</u>	<u>2.8 %</u>	<u>7.7 %</u>	<u>(25.6)%</u>
GAAP research and development expense	\$ 11,410	\$ 7,784	\$ 36,741	\$ 28,850
Stock-based compensation expense	(1,241)	(1,289)	(3,809)	(4,615)
Non-GAAP research and development expense	<u>\$ 10,169</u>	<u>\$ 6,495</u>	<u>\$ 32,932</u>	<u>\$ 24,235</u>
GAAP sales and marketing expense	\$ 22,991	\$ 15,198	\$ 65,070	\$ 45,068
Stock-based compensation expense	(1,896)	(1,595)	(5,897)	(4,423)
Non-GAAP sales and marketing expense	<u>\$ 21,095</u>	<u>\$ 13,603</u>	<u>\$ 59,173</u>	<u>\$ 40,645</u>
GAAP general and administrative expense	\$ 9,719	\$ 9,050	\$ 36,316	\$ 30,512
Stock-based compensation expense	(1,587)	(3,310)	(7,470)	(12,146)
Non-GAAP general and administrative expense	<u>\$ 8,132</u>	<u>\$ 5,740</u>	<u>\$ 28,846</u>	<u>\$ 18,366</u>
GAAP total operating expense	\$ 44,120	\$ 32,032	\$ 138,127	\$ 104,430
Stock-based compensation expense	(4,724)	(6,194)	(17,176)	(21,184)
Non-GAAP total operating expense	<u>\$ 39,396</u>	<u>\$ 25,838</u>	<u>\$ 120,951</u>	<u>\$ 83,246</u>

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