

Outset Medical Reports First Quarter 2022 Financial Results

May 4, 2022

Revenue Grows 33.3% to \$30.6 million, Gross Margin expands 13.2 percentage points to 14.5% Year-over-Year

SAN JOSE, Calif.--(BUSINESS WIRE)--May 4, 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 first quarter ended March 31, 2022.

Recent Highlights

- Recorded net revenue of \$30.6 million in the first quarter of 2022, a 33.3% increase compared to \$22.9 million in the first quarter of 2021 and an 8.5% increase compared to \$28.2 million in the fourth quarter of 2021
- Achieved gross margin for the first quarter of 2022 of 14.5%, compared to 1.3% in the first quarter of 2021 and 11.8% in the fourth quarter of 2021
- Shipped record number of Tablo consoles for Home patients, reflecting continued momentum in health care providers establishing Home programs
- Presented three data sets at the National Kidney Foundation Spring Clinical Meeting highlighting the advantages of Tablo and potential cost benefits of earlier peritoneal to home hemodialysis conversion
- Appointed business leader Dale E. Jones to Board of Directors

"The first quarter of 2022 was marked by strong revenue growth and gross margin expansion, which resulted from the momentum we see among both acute care customers and providers expanding access to Tablo at Home," said Leslie Trigg, Chair and Chief Executive Officer. "As interest for Tablo accelerates across all market segments, we continued to expand gross margins, invest in innovation, and deliver consistent and predictable financial and operational results, increasing our confidence for sustained strong performance through 2022 and beyond."

First Quarter 2022 Financial Results

Revenue for the first quarter of 2022 was \$30.6 million, representing an increase of 33.3% compared to \$22.9 million in the first quarter of 2021. Product revenue for the first quarter of 2022 was \$25.7 million, representing an increase of 40.9% compared to \$18.2 million in the first quarter of 2021. Service and other revenue for the first quarter of 2022 was \$4.9 million, representing an increase of 3.8% compared to \$4.7 million in the first quarter of 2021.

Total gross profit for the first quarter of 2022 was \$4.4 million, compared to a gross profit of \$0.3 million for the first quarter of 2021. Total gross margin for the first quarter of 2022 was 14.5%, compared to 1.3% in the first quarter of 2021. On a non-GAAP basis, gross margin for the first quarter of 2022 improved to 14.8% from 1.6% in the first quarter of 2021. Product gross profit for the first quarter of 2022 was \$2.6 million, compared to (\$2.4) million of product gross loss in the first quarter of 2021. Product gross margin for the first quarter of 2022 was 10.0%, compared to (13.0)% in the first quarter of 2021. Service and other gross profit for the first quarter of 2022 was \$1.9 million, compared to \$2.7 million of service and other gross profit in the first quarter of 2022 was 38.6%, compared to 56.4% in the first quarter of 2021.

Operating expenses for the first quarter of 2022 were \$40.9 million, including research and development (R&D) expenses of \$10.8 million, sales and marketing (S&M) expenses of \$20.4 million, and general and administrative (G&A) expenses of \$9.7 million. This compared to operating expenses of \$30.0 million, including R&D expenses of \$7.6 million, S&M expenses of \$13.1 million, and G&A expenses of \$9.2 million in the first quarter of 2021.

Excluding stock-based compensation expense, non-GAAP operating expenses for the first quarter of 2022 were \$36.0 million, including R&D expenses of \$9.7 million, S&M expenses of \$18.7 million, and G&A expenses of \$7.7 million.

First quarter 2022 net loss was (\$36.9) million, or (\$0.78) per share, compared to net loss of (\$30.0) million, or (\$0.70) per share, for the same period in 2021. On a non-GAAP basis, net loss for the first quarter of 2022 was (\$31.9) million, or (\$0.67) per share, compared to non-GAAP net loss of (\$24.2) million, or (\$0.56) per share for the same period in 2021.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$335.6 million as of March 31, 2022.

Full Year 2022 Financial Guidance

Outset now projects revenue for the full year 2022 to range from \$144 million to \$150 million, which represents approximately 40% to 46% growth over the Company's fiscal year 2021 revenue. This compares to prior 2022 revenue guidance of \$142 million to \$150 million.

Webcast and Conference Call Details

Outset will host a conference call today, May 4, 2022, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its first quarter 2022 financial results. The dial-in numbers are (833) 614-1409 for domestic callers and (914) 987-7130 for international callers. The conference ID is 4094889. 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. Forwardlooking 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.

Outset Medical, Inc. Condensed Statements of Operations

(in thousands, except per share amounts)

(unaudited)

Three Months Ended

	Ma	arch 31,
	2022	2021
Revenue:		
Product revenue	\$ 25,664	\$ 18,210
Service and other revenue	4,886	4,706
Total revenue	30,550	22,916
Cost of revenue:		
Cost of product revenue (2)	23,110	20,577
Cost of service and other revenue	2,998	32,050_
Total cost of revenue	26,108	3 22,627
Gross profit (1)	4,442	289
Gross margin ⁽¹⁾	14.5	5 % 1.3 %
Operating expenses:		
Research and development (2)	10,831	7,570
Sales and marketing (2)	20,377	7 13,149
General and administrative (2)	9,709	9,246
Total operating expenses	40,917	29,965
Loss from operations	(36,475	(29,676)

Other income (expense):			
Interest income and other income, net	120		112
Interest expense	(422)		(422)
Loss before provision for income taxes	(36,777)		(29,986)
Provision for income taxes	115		39
Net loss	\$ (36,892)	\$	(30,025)
Net loss per share, basic and diluted	\$ (0.78)	\$	(0.70)
Shares used in computing net loss per share, basic and diluted	47,487	_	42,760

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

	Three Months Ended March 31,			
	 2022		2021	
Gross profit				
Product revenue	\$ 2,554	\$	(2,367)	
Service and other revenue	 1,888	_	2,656	
Total gross profit	\$ 4,442	\$	289	
Gross margin				
Product revenue	10.0	%	(13.0) %	
Service and other revenue	38.6	%	56.4 %	
Total gross margin	14.5	%	1.3 %	

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

	 March 31,			
	 2022		2021	
Cost of revenue	\$ 93	\$	75	
Research and development	1,158		1,165	
Sales and marketing	1,706		1,742	
General and administrative	 2,049		2,870	
Total stock-based compensation expense	\$ 5,006	\$	5,852	

Three Months Ended

Outset Medical, Inc. Condensed Balance Sheets

(in thousands, except per share amounts)

	M.	March 31, 2022 (Unaudited)		ember 31, 2021
	(Ur			(Unaudited)
Assets				
Current assets:				
Cash and cash equivalents	\$	114,346	\$	182,348
Short-term investments		187,921		157,140
Accounts receivable, net		26,899		25,600
Inventories		42,873		39,185
Prepaid expenses and other current assets		5,387		5,529
Total current assets		377,426		409,802
Restricted cash		33,311		33,311
Property and equipment, net		13,882		12,964
Operating lease right-of-use assets		6,962		7,231
Other assets		161		156
Total assets	\$	431,742	\$	463,464

Liabilities and stockholders' equity

Current liabilities:				
Accounts payable	\$	5,149	\$	1,763
Accrued compensation and related benefits		13,478		24,948
Accrued expenses and other current liabilities		18,610		13,789
Accrued warranty liability		3,628		3,704
Deferred revenue, current		6,833		6,340
Operating lease liabilities, current		1,192		1,151
Total current liabilities		48,890		51,695
Accrued interest, noncurrent		840		721
Deferred revenue, noncurrent		194		312
Operating lease liabilities, noncurrent		6,581		6,893
Term loan, noncurrent		29,784		29,762
Total liabilities		86,289		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 March 31, 2022 and December 31, 2021		_		_
Common stock, \$0.001 par value; 300,000 shares authorized as of March 31, 2022 and December 31, 2021;				
47,712 and 47,241 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively		48		47
Additional paid-in capital		1,008,940		1,000,212
Accumulated other comprehensive loss		(649)		(184)
Accumulated deficit	_	(662,886)	_	(625,994)
Total stockholders' equity		345,453		374,081
Total liabilities and stockholders' equity	\$	431,742	\$	463,464

Outset Medical, Inc.

Condensed Statements of Cash Flows

(in thousands) (unaudited)

Inree Months Ended March 31,		
	2021	
\$	(38,616)	
	(6,807)	
	2,218	
	(43,205)	
	328,283	
\$ 147,657 \$		
)) 3 (2)	2)	

⁽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):

	Ma	March 31,			
	2022		2021		
Cash and cash equivalents	\$ 114,346	- \$	251,767		
Restricted cash	33,311		33,311_		
Total cash, cash equivalents and restricted cash*	\$ 147,657	\$	285,078		

^{*} The total cash, including restricted cash, cash equivalents and investment securities as of March 31, 2022 was \$335.6 million; compared to \$310.8 million as of March 31, 2021.

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:

		March 31,			
	2	022		2021	
GAAP net loss per share, diluted	\$	(0.78)	\$	(0.70)	
Stock-based compensation expense		0.11		0.14	
Non-GAAP net loss per share, diluted	\$	(0.67)	\$	(0.56)	

Reconciliation between GAAP and non-GAAP net loss:

	 March 31,			
	2022 20		2021	
GAAP net loss, diluted	\$ (36,892)	\$	(30,025)	
Stock-based compensation expense	 5,006		5,852	
Non-GAAP net loss, diluted	\$ (31,886)	\$	(24,173)	

Three Months Ended

Three Months Ended

Reconciliation between GAAP and non-GAAP results of operations:

		March 31,		
		2022		2021
GAAP gross profit	\$	4,442	\$	289
Stock-based compensation expense		93_		75_
Non-GAAP gross profit	\$	4,535	\$	364
GAAP gross margin		14.5 %	ı	1.3 %
Stock-based compensation expense		0.3		0.3
Non-GAAP gross margin	_	14.8 %		1.6 %
GAAP research and development expense	\$	10,831	\$	7,570
Stock-based compensation expense		(1,158)		(1,165)
Non-GAAP research and development expense	\$	9,673	\$	6,405
GAAP sales and marketing expense	\$	20,377	\$	13,149
Stock-based compensation expense		(1,706)		(1,742)
Non-GAAP sales and marketing expense	\$	18,671	\$	11,407
GAAP general and administrative expense	\$	9,709	\$	9,246
Stock-based compensation expense		(2,049)		(2,870)
Non-GAAP general and administrative expense	\$	7,660	\$	6,376
GAAP total operating expense	\$	40,917	\$	29,965
Stock-based compensation expense		(4,913)		(5,777)
Non-GAAP total operating expense	\$	36,004	\$	24,188

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