

Outset Medical Reports First Quarter 2023 Financial Results

May 3, 2023

Increases Revenue and Gross Margin Guidance for 2023

SAN JOSE, Calif.--(BUSINESS WIRE)--May 3, 2023-- 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, 2023.

Recent Highlights

- Recorded net revenue of \$33.5 million in the first quarter, a 9.5% increase compared to \$30.6 million in the first quarter of 2022, and a 4.6% increase compared to \$32.0 million in the fourth quarter of 2022
- Achieved gross margin for the first quarter of 19.2% (20.3% on a non-GAAP basis), compared to 14.5% (14.8% on a non-GAAP basis) in the first quarter of 2022
- Added more than 30 new hospital sites during the first quarter as part of Outset's land and expand commercial strategy, the largest quarterly growth in new sites since 2021
- Presented <u>five data sets</u> at the National Kidney Foundation Spring Clinical Meetings highlighting the clinical and financial benefits of home hemodialysis and other pertinent topics related to kidney disease

"We had a strong start to 2023, with revenue growth ahead of our expectations and gross margins expanding for the 8 th consecutive quarter," said Leslie Trigg, Chair and Chief Executive Officer. "The momentum we had exiting 2022 carried through the first quarter of 2023 with the benefits of Tablo continuing to resonate with acute-care and home providers."

First Quarter 2023 Financial Results

Revenue for the first quarter of 2023 was \$33.5 million, representing an increase of 9.5% compared to \$30.6 million in the first quarter of 2022. Product revenue was \$27.8 million, representing an increase of 8.2% compared to \$25.7 million in the first quarter of 2022. Service and other revenue was \$5.7 million, representing an increase of 16.4% compared to \$4.9 million in the first quarter of 2022.

Total gross profit was \$6.4 million, compared to \$4.4 million for the first quarter of 2022. Total gross margin was 19.2%, compared to 14.5% in the first quarter of 2022. On a non-GAAP basis, gross margin improved to 20.3% from 14.8% in the first quarter of 2022. Product gross profit was \$7.0 million, compared to \$2.6 million of product gross profit in the first quarter of 2022. Product gross margin was 25.1%, compared to 10.0% in the first quarter of 2022. Service and other gross loss was (\$0.5) million, compared to \$1.9 million of service and other gross profit in the first quarter of 2022. Service and other gross margin was (9.4)%, compared to 38.6% in the first quarter of 2022.

Operating expenses were \$49.9 million, including research and development (R&D) expenses of \$13.8 million, sales and marketing (S&M) expenses of \$24.3 million, and general and administrative (G&A) expenses of \$11.8 million. This compared to operating expenses of \$40.9 million, including R&D expenses of \$10.8 million, S&M expenses of \$20.4 million, and G&A expenses of \$9.7 million in the first quarter of 2022.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$41.7 million, including R&D expenses of \$11.2 million, S&M expenses of \$21.7 million, and G&A expenses of \$8.8 million.

Net loss was (\$44.0) million, or (\$0.90) per share, compared to net loss of (\$36.9) million, or (\$0.78) per share, for the same period in 2022. On a non-GAAP basis, net loss was (\$35.4) million, or (\$0.72) per share, compared to non-GAAP net loss of (\$31.9) million, or (\$0.67) per share for the same period in 2022.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$252.5 million as of March 31, 2023.

Full Year 2023 Financial Guidance

Outset now projects revenue for 2023 to range from \$144 million to \$150 million, which represents approximately 25% to 30% growth over the Company's fiscal year 2022 revenue. This updated guidance compares to prior 2023 revenue guidance of \$140 million to \$150 million. In addition, the Company expects gross margin for the year to be in the low-20% range, up from its prior guidance of approximately 20%, and exiting the fourth quarter in the mid-20% range.

Webcast and Conference Call Details

Outset will host a conference call today, May 3, 2023, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its first quarter 2023 financial results. Those interested in listening to the conference call may do so by registering online. Once registered, participants will receive dial-in numbers and a unique pin to join the call. Participants are encouraged to register more than 15 minutes before the start of the call. 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 our products, expand gross margins, further secure supply continuity and otherwise mitigate supply chain challenges and its ability to achieve projected cost reductions and other anticipated benefits from these initiatives at the levels or within the timeframe estimated; as well as the Company's expectations regarding the impact of macroeconomic factors on the Company, 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 the Company's public filings with the Securities and Exchange Commission, including its latest annual and guarterly 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

		March 31,		
	2	2023	2022	
Revenue:				
Product revenue	\$	27,779 \$	25,664	
Service and other revenue		5,688	4,886_	
Total revenue		33,467	30,550	
Cost of revenue:				
Cost of product revenue (2)		20,817	23,110	
Cost of service and other revenue		6,222	2,998_	
Total cost of revenue		27,039	26,108_	
Gross profit (1)		6,428	4,442	
Gross margin ⁽¹⁾		19.2 %	14.5 %	
Operating expenses:				
Research and development (2)		13,793	10,831	
Sales and marketing (2)		24,333	20,377	
General and administrative (2)		11,787	9,709_	
Total operating expenses		49,913	40,917	
Loss from operations		(43,485)	(36,475)	
Interest income and other income, net		2,648	120	
Interest expense		(2,942)	(422)	
Loss before provision for income taxes		(43,779)	(36,777)	

Provision for income taxes		192		192		115
Net loss	\$	(43,971)	\$	(36,892)		
Net loss per share, basic and diluted	\$	(0.90)	\$	(0.78)		
Shares used in computing net loss per share, basic and diluted		48,783		47,487		

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

Three Months Ended

Warch 31,			
2023			2022
\$	6,962	\$	2,554
	(534)		1,888
\$	6,428	\$	4,442
	25.1 %	, 0	10.0 %
	(9.4) %	, 0	38.6 %
	19.2 %	, D	14.5 %
	\$	\$ 6,962 (534) \$ 6,428 25.1 % (9.4) %	\$ 6,962 \$ (534)

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

Three Months Ended March 31,

	<u></u>	2023		2022
Cost of revenue	\$	358	\$	93
Research and development		2,615		1,158
Sales and marketing		2,598		1,706
General and administrative		2,967		2,049
Total stock-based compensation expense	\$	8,538	\$	5,006

Outset Medical, Inc. Condensed Balance Sheets

(in thousands, except per share amounts)

	N	March 31, 2023		•		,		ember 31, 2022
	(U	naudited)						
Assets								
Current assets:								
Cash and cash equivalents	\$	36,386	\$	73,222				
Short-term investments		212,827		214,280				
Accounts receivable, net		34,314		28,070				
Inventories		47,733		51,476				
Prepaid expenses and other current assets		6,015		6,597				
Total current assets		337,275		373,645				
Restricted cash		3,311		3,311				
Property and equipment, net		15,189		15,876				
Operating lease right-of-use assets		5,823		6,117				
Other assets		1,067		1,166_				
Total assets	\$	362,665	\$	400,115				
Liabilities and stockholders' equity								
Current liabilities:								
Accounts payable	\$	1,988	\$	603				
Accrued compensation and related benefits		14,419		21,519				
Accrued expenses and other current liabilities		13,893		16,227				
Accrued warranty liability		3,569		3,620				
Deferred revenue, current		9,038		8,662				
Operating lease liabilities, current		1,361		1,318				

Total current liabilities	44,268	51,949
Accrued interest	295	113
Deferred revenue	116	151
Operating lease liabilities	5,220	5,576
Term loan	96,480	96,336
Total liabilities	146,379	154,125
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, 2023 and December 31, 2022	_	_
Common stock, \$0.001 par value; 300,000 shares authorized as of March 31, 2023 and December 31, 2022; 49,216 and 48,465 shares issued and outstanding as of March 31, 2023 and December 31, 2022,		
respectively	49	48
Additional paid-in capital	1,049,271	1,035,456
Accumulated other comprehensive loss	(113)	(564)
Accumulated deficit	(832,921)	(788,950)
Total stockholders' equity	216,286	245,990
Total liabilities and stockholders' equity	\$ 362,665	\$ 400,115

Outset Medical, Inc. Condensed Statements of Cash Flows

(in thousands) (unaudited)

2023		0000
2023		2022
(44,756)	\$	(38,335)
2,643		(33,390)
5,277		3,723
(36,836)		(68,002)
76,533		215,659
39,697	\$	147,657
	2,643 5,277 (36,836) 76,533	5,277 (36,836) 76,533

⁽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,			
	2023		2022		
Cash and cash equivalents	\$ 36,	386 \$	114,346		
Restricted cash	3,	311	33,311		
Total cash, cash equivalents and restricted cash*	\$ 39,	397 \$	147,657		

^{*} The total cash, including restricted cash, cash equivalents and investment securities as of March 31, 2023 was \$252.5 million; compared to \$335.6 million as of March 31, 2022.

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:

GAAP net loss per share, diluted

Stock-based compensation expense

Three Months Ended March 31,

 2023		2022	
\$ (0.90)	\$	(0.78)	
0.18		0.11	

Reconciliation between GAAP and non-GAAP net loss:

Three Months Ended March 31,

	2023	2022	
GAAP net loss, diluted	\$ (43,971)	\$	(36,892)
Stock-based compensation expense	 8,538		5,006
Non-GAAP net loss, diluted	\$ (35,433)	\$	(31,886)

Reconciliation between GAAP and non-GAAP results of operations:

Three Months Ended March 31,

	 2023	2022
GAAP gross profit	\$ 6,428	\$ 4,442
Stock-based compensation expense	 358	 93
Non-GAAP gross profit	\$ 6,786	\$ 4,535
GAAP gross margin	19.2 %	14.5 %
Stock-based compensation expense	1.1	 0.3
Non-GAAP gross margin	 20.3 %	 14.8 %
GAAP research and development expense	\$ 13,793	\$ 10,831
Stock-based compensation expense	(2,615)	 (1,158)
Non-GAAP research and development expense	\$ 11,178	\$ 9,673
GAAP sales and marketing expense	\$ 24,333	\$ 20,377
Stock-based compensation expense	 (2,598)	 (1,706)
Non-GAAP sales and marketing expense	\$ 21,735	\$ 18,671
GAAP general and administrative expense	\$ 11,787	\$ 9,709
Stock-based compensation expense	 (2,967)	 (2,049)
Non-GAAP general and administrative expense	\$ 8,820	\$ 7,660
GAAP total operating expense	\$ 49,913	\$ 40,917
Stock-based compensation expense	(8,180)	 (4,913)
Non-GAAP total operating expense	\$ 41,733	\$ 36,004

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Investor Contact

Jim Mazzola
Outset Medical
858-342-8272
imazzola@outsetmedical.com

Media Contact

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

Source: Outset Medical, Inc.