



Outset Medical Reports First Quarter 2024 Financial Results

May 8, 2024

SAN JOSE, Calif.--(BUSINESS WIRE)--May 8, 2024-- 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, 2024.

"With our recent 510(k) clearance for TabloCart with Prefiltration, 12th consecutive quarter of gross margin expansion and strong sales pipeline growth during the quarter, we are well positioned to capitalize on the \$11 billion U.S. dialysis market opportunity," said Leslie Trigg, Chair and Chief Executive Officer. "Tablo's uniquely compelling value proposition continues to resonate with acute- and home-care providers, with significant new customer wins in both settings during the quarter.

"We also took cost-reduction steps during the quarter to help ensure we reach our profitability goals without the need for additional capital. We believe these actions, combined with continued gross margin expansion and a strong recurring revenue foundation, now provide us a clear path to achieve cash-flow breakeven sooner than previously expected."

First Quarter 2024 Financial Results

Revenue for the first quarter of 2024 was \$28.2 million compared to \$33.5 million in the first quarter of 2023, driven by an expected decline in product revenue to \$20.4 million. Service and other revenue was \$7.7 million, an increase of 36.1% compared to \$5.7 million in the first quarter of 2023. Recurring revenue from the sale of Tablo cartridges and service increased by 24% as compared to the prior-year period.

Total gross profit was \$8.2 million, compared to \$6.4 million for the first quarter of 2023. Total gross margin was 29.2%, compared to 19.2% in the first quarter of 2023. On a non-GAAP basis, gross margin improved to 31.1% from 20.3% in the first quarter of 2023. Product gross profit was \$7.8 million, compared to \$7.0 million of product gross profit in the first quarter of 2023. Product gross margin was 38.4%, compared to 25.1% in the first quarter of 2023. Service and other gross profit was \$0.4 million, compared to \$(0.5) million of service and other gross profit in the first quarter of 2023. Service and other gross margin was 4.8%, compared to (9.4)% in the first quarter of 2023.

Operating expenses declined 10% from the prior-year period to \$45.1 million, including research and development (R&D) expenses of \$12.6 million, sales and marketing (S&M) expenses of \$21.0 million, and general and administrative (G&A) expenses of \$11.4 million. This compared to operating expenses of \$49.9 million in the first quarter of 2023, including R&D expenses of \$13.8 million, S&M expenses of \$24.3 million, and G&A expenses of \$11.8 million.

Excluding stock-based compensation expense and severance and related charges, net of adjustments to compensation accrual, non-GAAP operating expenses were \$35.0 million, including R&D expenses of \$9.3 million, S&M expenses of \$18.8 million, and G&A expenses of \$6.9 million.

Net loss was \$(39.9) million, or \$(0.78) per share, compared to net loss of \$(44.0) million, or \$(0.90) per share, for the same period in 2023. On a non-GAAP basis, net loss was \$(29.3) million, or \$(0.57) per share, compared to non-GAAP net loss of \$(35.4) million, or \$(0.72) per share for the same period in 2023.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$230.2 million as of March 31, 2024.

Full Year 2024 Financial Guidance

Outset reaffirmed its previously provided guidance for 2024 including revenue of \$145 million to \$153 million, growing 12% to 18% over 2023, and non-GAAP gross margin in the low-30% range for the full year 2024, exiting the year in the mid-30% range for the fourth quarter.

Webcast and Conference Call Details

Outset will host a conference call today, May 8, 2024, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its first quarter 2024 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. As listed in the itemized reconciliations between GAAP and non-GAAP financial measures included in this press release, the Company's GAAP financial measures include stock-based compensation expense, as well as severance and related charges net of the reversal of compensation accruals for impacted employees. Stock-based compensation is a non-cash expense, and severance and related charges arise outside the ordinary course of continuing operations and are not reflective of the Company's current operating performance. As such, management has excluded the effects of these items 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, gross margin, operating expenses, capital expenditures, cash burn, cash position, profitability and outlook; statements about the Company's ability to meet its profitability goals without the need for additional capital and expectations on the timing of achieving cash-flow breakeven; statements regarding the anticipated impacts and benefits of the Company's cost reduction actions; 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 expand gross margins; the Company's ability to respond to and resolve any reports, observations or other actions by the Food and Drug Administration or other regulators in a timely and effective manner; 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 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	
	March 31,	
	2024	2023
Revenue:		
Product revenue	\$ 20,428	\$ 27,779
Service and other revenue	7,740	5,688
Total revenue	<u>28,168</u>	<u>33,467</u>
Cost of revenue:		
Cost of product revenue ⁽²⁾	12,581	20,817
Cost of service and other revenue	<u>7,372</u>	<u>6,222</u>
Total cost of revenue	<u>19,953</u>	<u>27,039</u>
Gross profit ⁽¹⁾	8,215	6,428
Gross margin ⁽¹⁾	29.2%	19.2%
Operating expenses:		
Research and development ⁽²⁾	12,635	13,793
Sales and marketing ⁽²⁾	21,048	24,333
General and administrative ⁽²⁾	<u>11,444</u>	<u>11,787</u>
Total operating expenses	<u>45,127</u>	<u>49,913</u>
Loss from operations	(36,912)	(43,485)
Interest income and other income, net	3,098	2,648
Interest expense	<u>(5,968)</u>	<u>(2,942)</u>
Loss before provision for income taxes	(39,782)	(43,779)
Provision for income taxes	<u>162</u>	<u>192</u>
Net loss	<u>\$ (39,944)</u>	<u>\$ (43,971)</u>

Net loss per share, basic and diluted	\$ (0.78)	\$ (0.90)
Shares used in computing net loss per share, basic and diluted	<u>50,901</u>	<u>48,783</u>

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

	Three Months Ended March 31,	
	2024	2023
Gross profit		
Product revenue	\$ 7,847	\$ 6,962
Service and other revenue	368	(534)
Total gross profit	<u>\$ 8,215</u>	<u>\$ 6,428</u>
Gross margin		
Product revenue	38.4%	25.1%
Service and other revenue	4.8%	(9.4)%
Total gross margin	29.2%	19.2%

(2) Include stock-based compensation expense and severance and related charges, net as follows:

	Three Months Ended March 31,	
	2024	2023
<u>Stock-based compensation expense</u>		
Cost of revenue	\$ 265	\$ 358
Research and development	2,332	2,615
Sales and marketing	1,459	2,598
General and administrative	4,147	2,967
Total stock-based compensation expense	<u>\$ 8,203</u>	<u>\$ 8,538</u>

	Three Months Ended March 31,	
	2024	2023
<u>Severance and related charges, net*</u>		
Cost of revenue	\$ 279	\$ —
Research and development	990	—
Sales and marketing	793	—
General and administrative	411	—
Total severance and related charges, net	<u>\$ 2,473</u>	<u>\$ —</u>

* Net of adjustments to compensation accrual

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

	March 31, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 32,176	\$ 68,509
Short-term investments	194,743	134,815
Accounts receivable, net	36,478	32,980
Inventories	55,839	49,215
Prepaid expenses and other current assets	6,155	5,700
Total current assets	<u>325,391</u>	<u>291,219</u>
Restricted cash	3,329	3,329
Property and equipment, net	11,953	13,273
Operating lease right-of-use assets	5,029	5,375
Other assets	540	605
Total assets	<u>\$ 346,242</u>	<u>\$ 313,801</u>

Liabilities and stockholders' equity

Current liabilities:

Accounts payable	\$ 6,773	\$ 5,827
Accrued compensation and related benefits	14,248	19,005
Accrued expenses and other current liabilities	11,968	13,459
Accrued warranty liability	3,200	3,712
Deferred revenue, current	12,839	11,727
Operating lease liabilities, current	1,642	1,593
Total current liabilities	<u>50,670</u>	<u>55,323</u>
Accrued interest	1,319	896
Deferred revenue	186	101
Operating lease liabilities	4,054	4,482
Term loans	196,813	130,113
Total liabilities	<u>253,042</u>	<u>190,915</u>

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, 2024 and December 31, 2023

Common stock, \$0.001 par value; 300,000 shares authorized as of March 31, 2024 and December 31, 2023; 51,702 and 50,317 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively

Additional paid-in capital	1,095,097	1,084,515
Accumulated other comprehensive income (loss)	(258)	68
Accumulated deficit	(1,001,691)	(961,747)
Total stockholders' equity	<u>93,200</u>	<u>122,886</u>
Total liabilities and stockholders' equity	<u>\$ 346,242</u>	<u>\$ 313,801</u>

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

	<u>Three Months Ended March 31,</u>	
	<u>2024</u>	<u>2023</u>
Net cash used in operating activities	\$ (45,912)	\$ (44,756)
Net cash (used in) provided by investing activities	(59,031)	2,643
Net cash provided by financing activities	68,610	5,277
Net decrease in cash, cash equivalents and restricted cash	(36,333)	(36,836)
Cash, cash equivalents and restricted cash at beginning of the period	71,838	76,533
Cash, cash equivalents and restricted cash at end of the period ⁽¹⁾	<u>\$ 35,505</u>	<u>\$ 39,697</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):

	<u>March 31,</u>	
	<u>2024</u>	<u>2023</u>
Cash and cash equivalents	\$ 32,176	\$ 36,386
Restricted cash	3,329	3,311
Total cash, cash equivalents and restricted cash *	<u>\$ 35,505</u>	<u>\$ 39,697</u>

* The total cash, including restricted cash, cash equivalents and investment securities as of March 31, 2024 was \$230.2 million; compared to \$252.5 million as of March 31, 2023.

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:

	Three Months Ended March 31,	
	2024	2023
GAAP net loss per share, diluted	\$ (0.78)	\$ (0.90)
Stock-based compensation expense	0.16	0.18
Severance and related charges, net	0.05	—
Non-GAAP net loss per share, diluted	<u>\$ (0.57)</u>	<u>\$ (0.72)</u>

Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended March 31,	
	2024	2023
GAAP net loss, diluted	\$ (39,944)	\$ (43,971)
Stock-based compensation expense	8,203	8,538
Severance and related charges, net	2,473	—
Non-GAAP net loss, diluted	<u>\$ (29,268)</u>	<u>\$ (35,433)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended March 31,	
	2024	2023
GAAP gross profit	\$ 8,215	\$ 6,428
Stock-based compensation expense	265	358
Severance and related charges, net	279	—
Non-GAAP gross profit	<u>\$ 8,759</u>	<u>\$ 6,786</u>
GAAP gross margin	29.2%	19.2%
Stock-based compensation expense	0.9	1.1
Severance and related charges, net	1.0	—
Non-GAAP gross margin	<u>31.1%</u>	<u>20.3%</u>
GAAP research and development expense	\$ 12,635	\$ 13,793
Stock-based compensation expense	(2,332)	(2,615)
Severance and related charges, net	(990)	—
Non-GAAP research and development expense	<u>\$ 9,313</u>	<u>\$ 11,178</u>
GAAP sales and marketing expense	\$ 21,048	\$ 24,333
Stock-based compensation expense	(1,459)	(2,598)
Severance and related charges, net	(793)	—
Non-GAAP sales and marketing expense	<u>\$ 18,796</u>	<u>\$ 21,735</u>
GAAP general and administrative expense	\$ 11,444	\$ 11,787
Stock-based compensation expense	(4,147)	(2,967)
Severance and related charges, net	(411)	—
Non-GAAP general and administrative expense	<u>\$ 6,886</u>	<u>\$ 8,820</u>
GAAP total operating expense	\$ 45,127	\$ 49,913
Stock-based compensation expense	(7,938)	(8,180)
Severance and related charges, net	(2,194)	—
Non-GAAP total operating expense	<u>\$ 34,995</u>	<u>\$ 41,733</u>

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