



Outset Medical Reports Third Quarter 2023 Financial Results

November 7, 2023

Reiterates Updated 2023 Revenue Guidance of Approximately \$130 Million

SAN JOSE, Calif.--(BUSINESS WIRE)--Nov. 7, 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 third quarter ended September 30, 2023.

Revenue for the third quarter was \$30.4 million, a 9% increase over revenue of \$27.8 million in the third quarter of 2022, and gross margin was 23.6%, or 25.6% on a non-GAAP basis, compared to 16.4% on a non-GAAP basis in the third quarter of 2022. Total cash, including restricted cash, cash equivalents and short-term investments, was \$197 million as of September 30, 2023.

"Our third quarter results were in line with the expectations we set in October, and our focus remains on ensuring the benefits of Tablo reach as many providers and patients as possible this year and well into the future," said Leslie Trigg, Chair and Chief Executive Officer. "All of the structural tailwinds for Tablo remain firmly in place, and we have high confidence in our ability to generate sustained long-term growth, achieve our gross margin goals, and reach profitability."

Third Quarter 2023 Financial Results

Revenue for the quarter was \$30.4 million, including product revenue of \$23.5 million, an increase of 8.2% compared to \$21.7 million in the third quarter of 2022, and service and other revenue of \$6.8 million, an increase of 13.4% compared to \$6.0 million in the third quarter of 2022.

Total gross profit was \$7.2 million, compared to \$4.3 million for the third quarter of 2022. Total gross margin was 23.6%, compared to 15.6% in the third quarter of 2022. On a non-GAAP basis, gross margin improved to 25.6% from 16.4% in the third quarter of 2022. Product gross profit was \$6.7 million, compared to \$2.1 million of product gross profit in the third quarter of 2022. Product gross margin was 28.4%, compared to 9.7% in the third quarter of 2022. Service and other gross profit was \$0.5 million, compared to \$2.2 million of service and other gross profit in the third quarter of 2022. Service and other gross margin was 6.8%, compared to 37.0% in the third quarter of 2022.

Operating expenses were \$52.6 million, including research and development (R&D) expenses of \$16.1 million, sales and marketing (S&M) expenses of \$24.7 million, and general and administrative (G&A) expenses of \$11.8 million. This compared to operating expenses of \$45.3 million, including R&D expenses of \$13.1 million, S&M expenses of \$22.3 million, and G&A expenses of \$10.0 million in the third quarter of 2022.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$42.3 million, including R&D expenses of \$13.3 million, S&M expenses of \$21.0 million, and G&A expenses of \$8.1 million.

Net loss was (\$46.2) million, or (\$0.93) per share, compared to net loss of (\$40.8) million, or (\$0.85) per share, for the same period in 2022. On a non-GAAP basis, net loss was (\$35.3) million, or (\$0.71) per share, compared to non-GAAP net loss of (\$33.4) million, or (\$0.70) per share for the same period in 2022.

Full Year 2023 Financial Guidance

Outset reiterated its 2023 revenue guidance of approximately \$130 million and its previous gross margin guidance for the year to be in the low-20% range, exiting the fourth quarter in the mid-20% range.

Webcast and Conference Call Details

Outset will host a conference call today, November 7, 2023, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its third 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. 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, 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 expand gross margins; our ability to respond to and resolve any reports, observations or other actions by the Food and Drug Administration (FDA) 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		Nine Months Ended	
	September 30,		September 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	\$ 23,531	\$ 21,739	\$ 80,640	\$ 67,024
Service and other revenue	6,831	6,022	19,229	16,344
Total revenue	30,362	27,761	99,869	83,368
Cost of revenue:				
Cost of product revenue ⁽²⁾	16,837	19,632	59,866	60,460
Cost of service and other revenue	6,368	3,793	18,715	10,348
Total cost of revenue	23,205	23,425	78,581	70,808
Gross profit ⁽¹⁾	7,157	4,336	21,288	12,560
Gross margin ⁽¹⁾	23.6 %	15.6 %	21.3 %	15.1 %
Operating expenses:				
Research and development ⁽²⁾	16,076	13,059	44,775	37,411
Sales and marketing ⁽²⁾	24,720	22,276	74,038	65,851
General and administrative ⁽²⁾	11,815	10,000	34,892	30,493
Total operating expenses	52,611	45,335	153,705	133,755
Loss from operations	(45,454)	(40,999)	(132,417)	(121,195)
Interest income and other income, net	2,573	805	7,889	1,384
Interest expense	(3,213)	(567)	(9,258)	(1,470)
Loss before provision for income taxes	(46,094)	(40,761)	(133,786)	(121,281)
Provision for income taxes	86	20	411	231
Net loss	<u>\$ (46,180)</u>	<u>\$ (40,781)</u>	<u>\$ (134,197)</u>	<u>\$ (121,512)</u>
Net loss per share, basic and diluted	<u>\$ (0.93)</u>	<u>\$ (0.85)</u>	<u>\$ (2.72)</u>	<u>\$ (2.54)</u>
Shares used in computing net loss per share, basic and diluted	<u>49,913</u>	<u>48,129</u>	<u>49,364</u>	<u>47,835</u>

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

Three Months Ended

Nine Months Ended

	September 30,		September 30,	
	2023	2022	2023	2022
Gross profit				
Product revenue	\$ 6,694	\$ 2,107	\$ 20,774	\$ 6,564
Service and other revenue	463	2,229	514	5,996
Total gross profit	<u>\$ 7,157</u>	<u>\$ 4,336</u>	<u>\$ 21,288</u>	<u>\$ 12,560</u>
Gross margin				
Product revenue	28.4 %	9.7 %	25.8 %	9.8 %
Service and other revenue	6.8 %	37.0 %	2.7 %	36.7 %
Total gross margin	23.6 %	15.6 %	21.3 %	15.1 %

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Cost of revenue	\$ 620	\$ 210	\$ 1,381	\$ 493
Research and development	2,793	1,919	8,232	4,885
Sales and marketing	3,765	2,870	9,908	7,440
General and administrative	3,715	2,431	10,015	7,032
Total stock-based compensation expense	<u>\$ 10,893</u>	<u>\$ 7,430</u>	<u>\$ 29,536</u>	<u>\$ 19,850</u>

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

	September 30, 2023 (Unaudited)	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,297	\$ 73,222
Short-term investments	157,701	214,280
Accounts receivable, net	35,493	28,070
Inventories	48,257	51,476
Prepaid expenses and other current assets	6,026	6,597
Total current assets	283,774	373,645
Restricted cash	3,329	3,311
Property and equipment, net	13,774	15,876
Operating lease right-of-use assets	5,713	6,117
Other assets	961	1,166
Total assets	<u>\$ 307,551</u>	<u>\$ 400,115</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 2,880	\$ 603
Accrued compensation and related benefits	21,544	21,519
Accrued expenses and other current liabilities	12,160	16,227
Accrued warranty liability	4,068	3,620
Deferred revenue, current	10,828	8,662
Operating lease liabilities, current	1,544	1,318
Total current liabilities	53,024	51,949
Accrued interest	680	113
Deferred revenue	99	151
Operating lease liabilities	4,901	5,576
Term loan	96,784	96,336
Total liabilities	155,488	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 September 30, 2023 and December 31, 2022

Common stock, \$0.001 par value; 300,000 shares authorized as of September 30, 2023 and December 31, 2022; 50,173 and 48,465 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively

Additional paid-in capital

Accumulated other comprehensive loss

Accumulated deficit

Total stockholders' equity

Total liabilities and stockholders' equity

	—	—
	50	48
	1,075,413	1,035,456
	(253)	(564)
	(923,147)	(788,950)
	<u>152,063</u>	<u>245,990</u>
	<u>\$ 307,551</u>	<u>\$ 400,115</u>

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

	Nine Months Ended September 30,	
	2023	2022
Net cash used in operating activities	\$ (106,931)	\$ (111,222)
Net cash provided by (used in) investing activities	59,601	(14,547)
Net cash provided by financing activities	10,423	7,298
Net decrease in cash, cash equivalents and restricted cash	(36,907)	(118,471)
Cash, cash equivalents and restricted cash at beginning of the period	76,533	215,659
Cash, cash equivalents and restricted cash at end of the period ⁽¹⁾	<u>\$ 39,626</u>	<u>\$ 97,188</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):

	September 30,	
	2023	2022
Cash and cash equivalents	\$ 36,297	\$ 63,877
Restricted cash	3,329	33,311
Total cash, cash equivalents and restricted cash*	<u>\$ 39,626</u>	<u>\$ 97,188</u>

* The total cash, including restricted cash, cash equivalents and investment securities as of September 30, 2023 was \$197.3 million; compared to \$260.8 million as of September 30, 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:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net loss per share, diluted	\$ (0.93)	\$ (0.85)	\$ (2.72)	\$ (2.54)
Stock-based compensation expense	0.22	0.15	0.60	0.41
Non-GAAP net loss per share, diluted	<u>\$ (0.71)</u>	<u>\$ (0.70)</u>	<u>\$ (2.12)</u>	<u>\$ (2.13)</u>

Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP net loss, diluted	\$ (46,180)	\$ (40,781)	\$ (134,197)	\$ (121,512)
Stock-based compensation expense	10,893	7,430	29,536	19,850

Non-GAAP net loss, diluted	\$ (35,287)	\$ (33,351)	\$ (104,661)	\$ (101,662)
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Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
GAAP gross profit	\$ 7,157	\$ 4,336	\$ 21,288	\$ 12,560
Stock-based compensation expense	620	210	1,381	493
Non-GAAP gross profit	<u>\$ 7,777</u>	<u>\$ 4,546</u>	<u>\$ 22,669</u>	<u>\$ 13,053</u>
GAAP gross margin	23.6 %	15.6 %	21.3 %	15.1 %
Stock-based compensation expense	2.0	0.8	1.4	0.6
Non-GAAP gross margin	<u>25.6 %</u>	<u>16.4 %</u>	<u>22.7 %</u>	<u>15.7 %</u>
GAAP research and development expense	\$ 16,076	\$ 13,059	\$ 44,775	\$ 37,411
Stock-based compensation expense	(2,793)	(1,919)	(8,232)	(4,885)
Non-GAAP research and development expense	<u>\$ 13,283</u>	<u>\$ 11,140</u>	<u>\$ 36,543</u>	<u>\$ 32,526</u>
GAAP sales and marketing expense	\$ 24,720	\$ 22,276	\$ 74,038	\$ 65,851
Stock-based compensation expense	(3,765)	(2,870)	(9,908)	(7,440)
Non-GAAP sales and marketing expense	<u>\$ 20,955</u>	<u>\$ 19,406</u>	<u>\$ 64,130</u>	<u>\$ 58,411</u>
GAAP general and administrative expense	\$ 11,815	\$ 10,000	\$ 34,892	\$ 30,493
Stock-based compensation expense	(3,715)	(2,431)	(10,015)	(7,032)
Non-GAAP general and administrative expense	<u>\$ 8,100</u>	<u>\$ 7,569</u>	<u>\$ 24,877</u>	<u>\$ 23,461</u>
GAAP total operating expense	\$ 52,611	\$ 45,335	\$ 153,705	\$ 133,755
Stock-based compensation expense	(10,273)	(7,220)	(28,155)	(19,357)
Non-GAAP total operating expense	<u>\$ 42,338</u>	<u>\$ 38,115</u>	<u>\$ 125,550</u>	<u>\$ 114,398</u>

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