

# **Outset Medical Reports Second Quarter 2023 Financial Results**

August 2, 2023

Sequential Revenue Growth of 8%, Ninth Consecutive Quarter of Gross Margin Expansion

Announces Shipment Pause of TabloCart with Prefiltration Pending 510(k) Clearance

Reiterates 2023 Revenue Range of \$144 Million to \$150 Million

SAN JOSE, Calif.--(BUSINESS WIRE)--Aug. 2, 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 second quarter ended June 30, 2023.

#### **Recent Highlights**

- Recorded net revenue of \$36.0 million in the second quarter, a 44% increase compared to \$25.1 million in the second quarter of 2022, and an 8% increase compared to \$33.5 million in the first quarter of 2023.
- Achieved gross margin for the second quarter of 21.4% (22.5% on a non-GAAP basis), compared to 15.1% (15.9% on a non-GAAP basis) in the second quarter of 2022.
- Initiated the first Tablo home dialysis program with one of the country's largest health systems with plans to expand to multiple U.S. sites.
- Achieved the Company's goal of signing agreements with the majority of U.S. mid-sized dialysis providers, further
  expanding its reach to patients who choose to dialyze at home.

"Our momentum entering 2023 carried through the second quarter, led by the strong demand from hospitals due to the value realized from insourcing dialysis with Tablo," said Leslie Trigg, Chair and Chief Executive Officer. "As important, Tablo's unique ease of use and flexibility continues to drive patient interest and demand from home-care providers, including traditional acute-care providers."

The Company also announced it has paused the shipment of TabloCart with Prefiltration, an accessory for the Tablo System, pending the Food and Drug Administration's clearance of a 510(k) the Company plans to submit later this month.

"Since receiving the Warning Letter on July 6, we have made the decision to file a 510(k) for TabloCart with Prefiltration and pause distribution of the product until a 510(k) clearance has been granted," added Trigg. "As we look ahead to the second half of the year, we expect our strong momentum both in the acute and home end markets to continue to drive the business."

#### Second Quarter 2023 Financial Results

Revenue for the second quarter of 2023 was \$36.0 million, representing an increase of 43.8% compared to \$25.1 million in the second quarter of 2022. Product revenue was \$29.3 million, representing an increase of 49.5% compared to \$19.6 million in the second quarter of 2022. Service and other revenue was \$6.7 million, representing an increase of 23.4% compared to \$5.4 million in the second quarter of 2022.

Total gross profit was \$7.7 million, compared to \$3.8 million for the second quarter of 2022. Total gross margin was 21.4%, compared to 15.1% in the second quarter of 2022. On a non-GAAP basis, gross margin improved to 22.5% from 15.9% in the second quarter of 2022. Product gross profit was \$7.1 million, compared to \$1.9 million of product gross profit in the second quarter of 2022. Product gross margin was 24.3%, compared to 9.7% in the second quarter of 2022. Service and other gross profit was \$0.6 million, compared to \$1.9 million of service and other gross profit in the second quarter of 2022. Service and other gross margin was 8.7%, compared to 34.6% in the second quarter of 2022.

Operating expenses were \$51.2 million, including research and development (R&D) expenses of \$14.9 million, sales and marketing (S&M) expenses of \$25.0 million, and general and administrative (G&A) expenses of \$11.3 million. This compared to operating expenses of \$47.5 million, including R&D expenses of \$13.5 million, S&M expenses of \$23.2 million, and G&A expenses of \$10.8 million in the second quarter of 2022.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$41.5 million, including R&D expenses of \$12.1 million, S&M expenses of \$21.4 million, and G&A expenses of \$8.0 million.

Net loss was (\$44.0) million, or (\$0.90) per share, compared to net loss of (\$43.8) million, or (\$0.92) per share, for the same period in 2022. On a non-GAAP basis, net loss was (\$33.9) million, or (\$0.69) per share, compared to non-GAAP net loss of (\$36.4) million, or (\$0.77) per share for the same period in 2022.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$226.1 million as of June 30, 2023.

# Full Year 2023 Financial Guidance

Outset reiterated its 2023 revenue guidance range of \$144 million to \$150 million, and now expects to be at the low end of this range as a result of the shipment pause for TabloCart with Prefiltration. The Company reaffirmed its 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, August 2, 2023, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its second quarter 2023 financial results. Those

interested in listening to the conference call may do so by <u>registering online</u>. 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 <a href="https://investors.outsetmedical.com">https://investors.outsetmedical.com</a>. 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, 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 expand gross margins; our 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)

(in thousands, except per share amounts)
(unaudited)

	Three Months Ended June 30,				Six Months Ended June 30,				
		2023		2022		2023		2022	
Revenue:								_	
Product revenue	\$	29,330	\$	19,621	\$	57,109	\$	45,285	
Service and other revenue		6,710		5,436		12,398		10,322	
Total revenue		36,040		25,057		69,507		55,607	
Cost of revenue:									
Cost of product revenue (2)		22,212		17,718		43,029		40,828	
Cost of service and other revenue		6,125		3,557		12,347		6,555	
Total cost of revenue		28,337		21,275		55,376		47,383	
Gross profit (1)		7,703		3,782		14,131		8,224	
Gross margin <sup>(1)</sup>		21.4%		15.1%		20.3%		14.8%	
Operating expenses:									
Research and development (2)		14,906		13,521		28,699		24,352	
Sales and marketing (2)		24,985		23,198		49,318		43,575	
General and administrative (2)		11,290		10,784		23,077		20,493	

Total operating expenses	51,181	47,503	101,094	88,420
Loss from operations	 (43,478)	(43,721)	 (86,963)	 (80,196)
Interest income and other income, net	2,668	459	5,316	579
Interest expense	(3,103)	(481)	(6,045)	 (903)
Loss before provision for income taxes	(43,913)	(43,743)	(87,692)	(80,520)
Provision for income taxes	133	96	325	 211
Net loss	\$ (44,046)	\$ (43,839)	\$ (88,017)	\$ (80,731)
Net loss per share, basic and diluted Shares used in computing net loss per share, basic and diluted	\$ (0.90)	\$ (0.92)	\$ (1.79)	\$ (1.69)
	 48,951	47,882	49,085	47,686

<sup>(1)</sup> Gross profit and gross margin by source consisted of the following:

	 Three Months Ended June 30,					Six Months Ended June 30,				
	 2023		2022		2023		2022			
Gross profit										
Product revenue	\$ 7,118	\$	1,903	\$	14,080	\$	4,457			
Service and other revenue	 585		1,879		51		3,767			
Total gross profit	\$ 7,703	\$	3,782	\$	14,131	\$	8,224			
Gross margin										
Product revenue	24.3%	)	9.7%		24.7%		9.8%			
Service and other revenue	8.7%	)	34.6%		0.4%		36.5%			
Total gross margin	21.4%	•	15.1%	D	20.3%	•	14.8%			

<sup>(2)</sup> Include stock-based compensation expense as follows:

	Three Months Ended June 30,				Six Months Ended June 30,				
Cost of revenue		2023	10 00,	2022	-	2023	10 00,	2022	
	\$	403	\$	190	\$	761	\$	283	
Research and development		2,824		1,808		5,439		2,966	
Sales and marketing		3,545		2,864		6,143		4,570	
General and administrative		3,333		2,552		6,300		4,601	
Total stock-based compensation expense	\$	10,105	\$	7,414	\$	18,643	\$	12,420	

# Outset Medical, Inc. **Condensed Balance Sheets**

(in thousands, except per share amounts)

	 June 30, 2023		
	(Unaudited)		
Assets			
Current assets:			
Cash and cash equivalents	\$ 36,388	\$	73,222
Short-term investments	186,403		214,280
Accounts receivable, net	36,902		28,070
Inventories	44,495		51,476
Prepaid expenses and other current assets	 5,216		6,597
Total current assets	 309,404		373,645
Restricted cash	3,329		3,311
Property and equipment, net	14,539		15,876
Operating lease right-of-use assets	6,042		6,117
Other assets	 1,128		1,166_
Total assets	\$ 334,442	\$	400,115
Liabilities and stockholders' equity			
Current liabilities:			
Accounts payable	\$ 2,217	\$	603

Accrued compensation and related benefits	17,461		21,519
Accrued expenses and other current liabilities	12,650		16,227
Accrued warranty liability	4,168		3,620
Deferred revenue, current	10,854		8,662
Operating lease liabilities, current	1,474		1,318
Total current liabilities	48,824		51,949
Accrued interest	484		113
Deferred revenue	89		151
Operating lease liabilities	5,308		5,576
Term loan	96,629		96,336_
Total liabilities	151,334		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 June 30, 2023 and December 31, 2022	_	_	_
Common stock, \$0.001 par value; 300,000 shares authorized as of June 30, 2023 and December 31, 2022; 49,629 and 48,465 shares issued and outstanding as of June 30, 2023 and December			
31, 2022, respectively	50		48
Additional paid-in capital	1,060,418		1,035,456
Accumulated other comprehensive loss	(393)	)	(564)
Accumulated deficit	(876,967)	<u> </u>	(788,950)
Total stockholders' equity	183,108		245,990
Total liabilities and stockholders' equity	\$ 334,442	\$	400,115

# Outset Medical, Inc. Condensed Statements of Cash Flows

(in thousands) (unaudited)

	Six Months Ended June 30,				
		2023			
Net cash used in operating activities	\$	(72,932)	\$	(76,910)	
Net cash provided by (used in) investing activities		29,796		(34,706)	
Net cash provided by financing activities		6,320		4,765	
Net decrease in cash, cash equivalents and restricted cash		(36,816)		(106,851)	
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)	\$	39,717	\$	108,808	

<sup>(1)</sup> 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):

	 June 30,				
	 2023		2022		
Cash and cash equivalents	\$ 36,388	\$	75,497		
Restricted cash	 3,329		33,311		
Total cash, cash equivalents and restricted cash*	\$ 39,717	\$	108,808		

<sup>\*</sup> The total cash, including restricted cash, cash equivalents and investment securities as of June 30, 2023 was \$226.1 million; compared to \$295.4 million as of June 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	Six Months Ended
June 30,	June 30,

	2023		 2022	2023		2022	
GAAP net loss per share, diluted	\$	(0.90)	\$ (0.92)	\$	(1.79)	\$	(1.69)
Stock-based compensation expense		0.21	0.15		0.38		0.26
Non-GAAP net loss per share, diluted	\$	(0.69)	\$ (0.77)	\$	(1.41)	\$	(1.43)

# Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended				Six Months Ended				
		June 30,				June 30,			
	2023		2022		2023		2022		
GAAP net loss, diluted	\$	(44,046)	\$	(43,839)	\$	(88,017)	\$	(80,731)	
Stock-based compensation expense		10,105		7,414		18,643		12,420	
Non-GAAP net loss, diluted	\$	(33,941)	\$	(36,425)	\$	(69,374)	\$	(68,311)	

# Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended June 30,				Six Months Ended June 30,			
		2023		2022		2023		2022
GAAP gross profit Stock-based compensation expense	\$	7,703 403	\$	3,782 190	\$	14,131 761	\$	8,224 283
Non-GAAP gross profit	\$	8,106	\$	3,972	\$	14,892	\$	8,507
GAAP gross margin		21.4%		15.1%		20.3%		14.8%
Stock-based compensation expense		1.1		0.8		1.1		0.5
Non-GAAP gross margin		22.5%		15.9%		21.4%		15.3%
GAAP research and development expense	\$	14,906	\$	13,521	\$	28,699	\$	24,352
Stock-based compensation expense		(2,824)		(1,808)		(5,439)		(2,966)
Non-GAAP research and development expense	\$	12,082	\$	11,713	\$	23,260	\$	21,386
GAAP sales and marketing expense Stock-based compensation expense	\$	24,985 (3,545)	\$	23,198 (2,864)	\$	49,318 (6,143)	\$	43,575 (4,570)
Non-GAAP sales and marketing expense	\$	21,440	\$	20,334	\$	43,175	\$	39,005
GAAP general and administrative expense Stock-based compensation expense	\$	11,290 (3,333)	\$	10,784 (2,552)	\$	23,077 (6,300)	\$	20,493 (4,601)
Non-GAAP general and administrative expense	\$	7,957	\$	8,232	\$	16,777	\$	15,892
GAAP total operating expense Stock-based compensation expense	\$	51,181 (9,702)	\$	47,503 (7,224)	\$	101,094 (17,882)	\$	88,420 (12,137)
Non-GAAP total operating expense	\$	41,479	\$	40,279	\$	83,212	\$	76,283

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