

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2025

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number: 001-39513

Outset Medical, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
3052 Orchard Dr.
San Jose, California
(Address of principal executive offices)

20-0514392
(I.R.S. Employer
Identification No.)

95134
(Zip Code)

Registrant's telephone number, including area code: (669) 231-8200

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	OM	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

As of November 6, 2025, the registrant had 18,153,090 shares of common stock, \$0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited).

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

	September 30, 2025	December 31, 2024
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,437	\$ 124,014
Short-term investments	142,201	34,671
Accounts receivable, net	32,962	35,619
Inventories	49,289	59,387
Prepaid expenses and other current assets	4,478	4,530
Total current assets	265,367	258,221
Restricted cash	3,329	3,329
Property and equipment, net	5,254	8,133
Operating lease right-of-use assets	2,767	3,940
Other assets	538	2,172
Total assets	<u>\$ 277,255</u>	<u>\$ 275,795</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 1,724	\$ 3,862
Accrued compensation and related benefits	10,855	16,821
Accrued expenses and other current liabilities	6,692	8,205
Accrued warranty liability	1,363	1,938
Deferred revenue, current	14,900	12,753
Operating lease liabilities, current	1,912	1,799
Total current liabilities	37,446	45,378
Accrued interest	—	2,695
Deferred revenue	676	844
Operating lease liabilities	1,244	2,684
Term loans	95,524	197,375
Total liabilities	134,890	248,976
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred Stock, \$0.001 par value; 5,000 shares authorized as of September 30, 2025 and December 31, 2024; 21 and 0 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	3,841	—
Common stock, \$0.001 par value; 300,000 shares authorized as of September 30, 2025 and December 31, 2024; 17,809 and 3,530 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	18	4
Additional paid-in capital	1,290,234	1,116,496
Accumulated other comprehensive income	157	42
Accumulated deficit	(1,151,885)	(1,089,723)
Total stockholders' equity	142,365	26,819
Total liabilities and stockholders' equity	<u>\$ 277,255</u>	<u>\$ 275,795</u>

The accompanying notes are an integral part of these unaudited condensed financial statements.

Outset Medical, Inc.
Condensed Statements of Operations
(Unaudited)
(in thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue	\$ 20,558	\$ 20,305	\$ 64,934	\$ 59,971
Service and other revenue	8,873	8,361	25,668	24,251
Total revenue	29,431	28,666	90,602	84,222
Cost of revenue:				
Cost of product revenue	11,169	11,532	33,962	34,680
Cost of service and other revenue	6,672	7,314	22,117	21,725
Total cost of revenue	17,841	18,846	56,079	56,405
Gross profit	11,590	9,820	34,523	27,817
Operating expenses:				
Research and development	5,376	8,139	16,180	30,508
Sales and marketing	13,550	15,417	41,482	54,593
General and administrative	8,477	10,103	25,938	34,231
Total operating expenses	27,403	33,659	83,600	119,332
Loss from operations	(15,813)	(23,839)	(49,077)	(91,515)
Interest income and other income, net	1,855	2,149	5,734	7,718
Interest expense	(3,476)	(6,068)	(10,511)	(18,046)
Loss on extinguishment of term loan	—	—	(7,685)	—
Loss before provision for income taxes	(17,434)	(27,758)	(61,539)	(101,843)
Provision for income taxes	404	182	623	495
Net loss	\$ (17,838)	\$ (27,940)	\$ (62,162)	\$ (102,338)
Net loss per share, basic and diluted	\$ (1.00)	\$ (8.02)	\$ (4.37)	\$ (29.71)
Shares used in computing net loss per share, basic and diluted	17,783	3,484	14,228	3,445

The accompanying notes are an integral part of these unaudited condensed financial statements.

Outset Medical, Inc.
Condensed Statements of Comprehensive Loss
(Unaudited)
(in thousands)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss	\$ (17,838)	\$ (27,940)	\$ (62,162)	\$ (102,338)
Other comprehensive income:				
Unrealized gain on available-for-sale securities	108	654	115	284
Comprehensive loss	\$ (17,730)	\$ (27,286)	\$ (62,047)	\$ (102,054)

The accompanying notes are an integral part of these unaudited condensed financial statements.

Outset Medical, Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity
(Unaudited)
(in thousands)

	<u>Convertible Preferred Stock</u>		<u>Common Stock</u>		<u>Additional Paid-in Capital</u>	<u>Accumulated Other Comprehensive Income (Loss)</u>	<u>Accumulated Deficit</u>	<u>Total Stockholders' Equity</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>				
Balance as of December 31, 2024	—	\$ —	3,530	\$ 4	\$ 1,116,496	\$ 42	\$ (1,089,723)	\$ 26,819
Issuance of Series A convertible preferred stock, net of issuance costs	863	161,071	—	—	—	—	—	161,071
Conversion of convertible preferred stock to common stock	(842)	(157,230)	14,046	14	157,216	—	—	—
Issuance of common stock warrant, net of issuance costs	—	—	—	—	4,330	—	—	4,330
Issuance of common stock through employee stock purchase plan	—	—	60	—	408	—	—	408
Issuance of common stock for settlement of RSUs	—	—	86	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	2,977	—	—	2,977
Unrealized gain on available-for-sale securities	—	—	—	—	—	46	—	46
Net loss	—	—	—	—	—	—	(25,783)	(25,783)
Balance as of March 31, 2025	21	\$ 3,841	17,722	\$ 18	\$ 1,281,427	\$ 88	\$ (1,115,506)	\$ 169,868
Issuance of common stock for settlement of RSUs	—	—	44	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	3,496	—	—	3,496
Unrealized loss on available-for-sale securities	—	—	—	—	—	(39)	—	(39)
Net loss	—	—	—	—	—	—	(18,541)	(18,541)
Balance as of June 30, 2025	21	\$ 3,841	17,766	\$ 18	\$ 1,284,923	\$ 49	\$ (1,134,047)	\$ 154,784
Issuance of common stock through employee stock purchase plan	—	—	27	—	231	—	—	231
Issuance of common stock for settlement of RSUs	—	—	16	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	5,080	—	—	5,080
Unrealized gain on available-for-sale securities	—	—	—	—	—	108	—	108
Net loss	—	—	—	—	—	—	(17,838)	(17,838)
Balance as of September 30, 2025	21	\$ 3,841	17,809	\$ 18	\$ 1,290,234	\$ 157	\$ (1,151,885)	\$ 142,365

The accompanying notes are an integral part of these unaudited condensed financial statements.

Outset Medical, Inc.
Condensed Statements of Convertible Preferred Stock and Stockholders' Equity
(Unaudited)
(in thousands)

	Convertible Series A Preferred Stock		Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2023	—	\$ —	3,354	\$ 3	\$ 1,084,562	\$ 68	\$ (961,747)	\$ 122,886
Issuance of common stock through employee stock purchase plan	—	—	52	1	2,079	—	—	2,080
Issuance of common stock for settlement of RSUs	—	—	40	—	295	—	—	295
Stock option exercises	—	—	—	—	6	—	—	6
Stock-based compensation expense	—	—	—	—	8,203	—	—	8,203
Unrealized loss on available-for-sale securities	—	—	—	—	—	(326)	—	(326)
Net loss	—	—	—	—	—	—	(39,944)	(39,944)
Balance as of March 31, 2024	—	\$ —	3,446	\$ 4	\$ 1,095,145	\$ (258)	\$ (1,001,691)	\$ 93,200
Issuance of common stock for settlement of RSUs	—	—	21	—	—	—	—	—
Stock option exercises	—	—	5	—	77	—	—	77
Stock-based compensation expense	—	—	—	—	9,820	—	—	9,820
Unrealized loss on available-for-sale securities	—	—	—	—	—	(44)	—	(44)
Net loss	—	—	—	—	—	—	(34,454)	(34,454)
Balance as of June 30, 2024	—	\$ —	3,472	\$ 4	\$ 1,105,042	\$ (302)	\$ (1,036,145)	\$ 68,599
Issuance of common stock through employee stock purchase plan	—	—	18	—	121	—	—	121
Issuance of common stock for settlement of RSUs	—	—	13	—	—	—	—	—
Stock-based compensation expense	—	—	—	—	6,388	—	—	6,388
Unrealized gain on available-for-sale securities	—	—	—	—	—	654	—	654
Net loss	—	—	—	—	—	—	(27,940)	(27,940)
Balance as of September 30, 2024	—	\$ —	3,503	\$ 4	\$ 1,111,551	\$ 352	\$ (1,064,085)	\$ 47,822

The accompanying notes are an integral part of these unaudited condensed financial statements.

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

	Nine Months Ended September 30,	
	2025	2024
Cash flows from operating activities:		
Net loss	\$ (62,162)	\$ (102,338)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	11,553	24,411
Depreciation and amortization	3,460	4,322
Non-cash lease expense	1,173	1,063
Non-cash interest expense	2,045	1,898
Amortization of premium on investments, net	(1,717)	(3,890)
Change in provision for inventories	(203)	644
Change in provision for credit losses	650	1,813
Loss on disposal of property and equipment	5	34
Loss on extinguishment of term loan	7,685	—
Changes in operating assets and liabilities:		
Accounts receivable	2,007	(3,092)
Inventories	10,301	(12,989)
Prepaid expenses and other assets	360	1,848
Accounts payable	(2,164)	(1,507)
Accrued compensation and related benefits	(5,966)	(3,991)
Accrued expenses and other current liabilities	(1,216)	(6,327)
Accrued warranty liability	(575)	(1,556)
Deferred revenue	1,979	1,015
Operating lease liabilities	(1,326)	(1,173)
Accrued interest	(2,695)	—
Net cash used in operating activities	<u>(36,806)</u>	<u>(99,815)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(575)	(869)
Purchases of investment securities	(193,748)	(150,467)
Sales and maturities of investment securities	88,049	147,121
Net cash used in investing activities	<u>(106,274)</u>	<u>(4,215)</u>
Cash flows from financing activities:		
Proceeds from stock option exercises and ESPP purchases	639	2,284
Proceeds from issuance of term loans, net of issuance costs	98,270	66,524
Repayment of term loan and extinguishment costs	(204,954)	—
Proceeds from issuance of Series A convertible preferred stock, net of issuance costs	161,548	—
Net cash provided by financing activities	<u>55,503</u>	<u>68,808</u>
Net decrease in cash, cash equivalents and restricted cash	(87,577)	(35,222)
Cash, cash equivalents and restricted cash as of beginning of period	127,343	71,838
Cash, cash equivalents and restricted cash as of end of period	<u>\$ 39,766</u>	<u>\$ 36,616</u>
Summary of cash, cash equivalents and restricted cash reported within the balance sheets:		
Cash and cash equivalents	\$ 36,437	\$ 33,287
Restricted cash	3,329	3,329
Total cash, cash equivalents and restricted cash	<u>\$ 39,766</u>	<u>\$ 36,616</u>

The accompanying notes are an integral part of these unaudited condensed financial statements.

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

	Nine Months Ended September 30,	
	2025	2024
Supplemental cash flow disclosures:		
Cash paid for income taxes	\$ 328	\$ 472
Cash paid for interest	\$ 12,906	\$ 15,537
Cash paid for amounts included in the measurement of operating lease liabilities	\$ 1,326	\$ 1,173
Supplemental non-cash investing and financing activities:		
Transfer of inventories to property and equipment	\$ —	\$ 148
Fair value of common stock warrant	\$ 4,367	\$ —

The accompanying notes are an integral part of these unaudited condensed financial statements.

Outset Medical, Inc.
Notes to Unaudited Condensed Financial Statements

1. Description of Business

Outset Medical, Inc. (the Company) is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. Tablo® Hemodialysis System (Tablo), cleared by the U.S. Food and Drug Administration (FDA) for use from the hospital to the home, represents a significant technological advancement designed to transform the dialysis experience for patients and operationally simplify it for providers. Tablo serves as a single enterprise solution designed to be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere, and by virtually anyone. The integration of water purification and on-demand dialysate production in a single 35-inch compact console enables Tablo to serve as a dialysis clinic on wheels. With a simple-to-use touchscreen interface, two-way wireless data transmission and a proprietary data analytics platform, Tablo is a new holistic approach to dialysis care. The Company's headquarters are located in San Jose, California.

Reverse Stock Split

In March 2025, the Company's board of directors and shareholders approved a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation to effect a reverse split of shares of the Company's common stock on a 15-for-one basis (the Reverse Stock Split), which became effective as of March 20, 2025. The number of authorized shares and the par values of the common stock and preferred stock were not adjusted as a result of the Reverse Stock Split. In connection with the Reverse Stock Split, the conversion ratio for the Company's outstanding convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. Also, any outstanding common stock warrants were adjusted such that the common stock issuable upon exercise of such warrants were decreased in proportion to the Reverse Stock Split. In addition, the number of shares of common stock available for issuance under the Company's equity incentive plans and issuable upon the exercise of stock options, warrants and restricted stock units outstanding prior to the Reverse Stock Split were proportionately adjusted. No fractional shares were distributed as a result of the Reverse Stock Split and stockholders were entitled to a cash payment in lieu of fractional shares.

All common stock share and per share amounts and information presented herein have been retroactively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. During the nine months ended September 30, 2025 and 2024, the Company incurred a net loss of \$62.2 million and \$102.3 million, respectively, and cash outflow from operating activities of \$36.8 million and \$99.8 million, respectively. As of September 30, 2025, the Company had an accumulated deficit of \$1.2 billion.

As of September 30, 2025, the Company had cash, cash equivalents, restricted cash and short-term investments of \$182.0 million. In January and March 2025, the Company sold 863,000 shares of its Series A Non-Voting Convertible Preferred Stock (Series A Convertible Preferred Stock) at a price of \$200.00 per share in a private placement transaction (the Private Placement) for total gross proceeds of \$172.7 million, before deducting placement agent fees and other offering expenses. Subsequently, 842,000 shares of Series A Convertible Preferred Stock were converted into 14,046,000 shares of the Company's common stock. See Note 8 for further details.

In addition, in January 2025, the Company entered into a credit agreement and guaranty (the Perceptive Credit Agreement) with Perceptive Credit Holdings IV, LP, as administrative agent (Agent) and the lenders from time to time party thereto, which provided a \$100 million 5-year term loan at closing and provides an additional term loan of up to \$25 million, which is available for funding until July 14, 2027, subject to the achievement of certain revenue milestone and other customary conditions (the Perceptive Term Loan). The Company is required to comply with certain covenants under the Perceptive Credit Agreement including, among others, requirements as to financial reporting, restrictions on its ability to incur additional indebtedness and to pay any dividends or other distributions on capital stock, maintenance of a minimum cash balance, and achievement of certain specified trailing twelve-month net revenue targets. If the Company fails to comply with any covenants, payments or other terms of the Perceptive Credit Agreement and such failure constitutes an event of default, such event of default would give Agent the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. Further details of obligations under the Perceptive Credit Agreement are described in Note 7.

While the Company has taken actions to reduce operating expenses and working capital to align with anticipated revenue growth including implementing restructuring plans to streamline its overall organizational structure and renegotiating commitments with suppliers to reduce inventory, management expects to continue to incur operating losses in the near term while the Company makes investments to support its anticipated growth.

Management believes that the Company's existing cash, cash equivalents, short-term investments, cash generated from sales, and proceeds recently received from the debt financing described in Note 7 as well as proceeds received from the Private Placement described in Note 8, will be sufficient to meet its anticipated needs for at least the next 12 months from the issuance date of the accompanying condensed financial statements.

Basis of Presentation

The accompanying condensed financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, that are necessary for the fair statement of the Company's financial position, results of operations, comprehensive loss, and cash flows for the interim periods presented. The financial data and the other financial information disclosed in these notes to the condensed financial statements related to the three- and nine-month periods are also unaudited. The results of operations for the three and nine months ended September 30, 2025 are not necessarily indicative of the results of operations to be anticipated for any other future annual or interim period. The condensed balance sheet as of December 31, 2024 included herein was derived from the audited financial statements as of that date.

These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements and related notes for the year ended December 31, 2024, which are included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2024 filed with the Securities and Exchange Commission (SEC) on February 21, 2025 (2024 Annual Report).

All share amounts disclosed in the notes to the condensed financial statements are rounded to the nearest thousand except for per share data.

2. Summary of Significant Accounting Policies

With the exception of the new accounting policy and new accounting pronouncements below, there have been no other new or material changes to the Company's significant accounting policies as described in its 2024 Annual Report that have had a material impact on the Company's condensed financial statements and related notes.

Common Stock Warrant

The Company has accounted for its freestanding warrants to purchase shares of the Company's common stock as equity at fair value upon issuance primarily because the warrants are indexed to the Company's own common stock. The Company estimated the fair value of these warrants using the Black-Scholes option pricing model, which is considered to be a Level 3 fair value measurement. Assumptions used in the pricing model were based on the individual characteristics of the warrants on the valuation date, as well as assumptions for expected volatility, expected term, and risk-free interest rate.

Recently Issued Accounting Pronouncements Not Yet Adopted

In July 2025, the Financial Accounting Standards Board (FASB) issued Accounting Standards Updated (ASU) 2025-05, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets* (ASU 2025-05), which permits entities to elect a practical expedient to assume current conditions as of the balance sheet date will not change for the remaining life of accounts receivable and contract assets when developing forecasts as part of estimating expected credit losses. The amendments in ASU 2025-05 will be effective for fiscal years beginning after December 15, 2025, and interim periods within those fiscal years, with early adoption permitted. The amendments should be applied prospectively. The Company is currently evaluating this practical expedient and does not expect it to have a material impact on its financial statements.

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software (Subtopic 350-40): Targeted Improvements to the Accounting for Internal-Use Software* (ASU 2025-06), which removes all references to software development project stages and requires entities to start capitalizing software costs when both of the following occur: (i) management has authorized and committed to funding the software project and (ii) it is probable that the project will be completed and the software will be used to perform the function intended. The amendments in ASU 2025-06 will be effective for fiscal years beginning after December 15, 2027, and interim periods within those fiscal years, with early adoption permitted as of the beginning of a fiscal year. The amendments can be applied prospectively, retrospectively, or via a modified prospective transition method. The Company is currently evaluating the impact this guidance may have on its financial statements.

3. Revenue and Deferred Revenue

Disaggregation of Revenue

Revenue by source consists of the following (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Consoles	\$ 8,339	\$ 7,709	\$ 24,362	\$ 24,080
Consumables	12,219	12,596	40,572	35,891
Total product revenue	20,558	20,305	64,934	59,971
Service and other revenue	8,873	8,361	25,668	24,251
Total revenue	\$ 29,431	\$ 28,666	\$ 90,602	\$ 84,222

Remaining Performance Obligations and Contract Liabilities

As of September 30, 2025, the aggregate amount of the transaction price allocated to the remaining performance obligations related to customer service contracts that are unsatisfied or partially unsatisfied was \$15.6 million, which is recorded as deferred revenue on the Company's condensed balance sheets. Of that amount, \$14.9 million will be recognized as revenue during the next 12 months and \$0.7 million thereafter.

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition. Revenue under these agreements is recognized over the related service period. During the three and nine months ended September 30, 2025, the Company recognized \$2.0 million and \$10.2 million of previously deferred revenue, respectively.

4. Fair Value Measurements

The following tables summarize the Company's financial assets measured at fair value on a recurring basis by level within the fair value hierarchy (in thousands):

	Valuation Hierarchy	September 30, 2025			
		Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	\$ 24,363	\$ —	\$ —	\$ 24,363
Short-term investments:					
U.S. Treasury securities	Level 1	86,748	81	(6)	86,823
Corporate debt	Level 2	48,287	75	(3)	48,359
Commercial paper	Level 2	3,911	5	—	3,916
Foreign entity bond	Level 2	3,098	5	—	3,103
Total cash equivalents and short-term investments		\$ 166,407	\$ 166	\$ (9)	\$ 166,564

	Valuation Hierarchy	December 31, 2024			
		Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	\$ 110,979	\$ —	\$ —	\$ 110,979
Short-term investments:					
Corporate debt	Level 2	34,629	43	(1)	34,671
Total cash equivalents and short-term investments		\$ 145,608	\$ 43	\$ (1)	\$ 145,650

As of September 30, 2025, the remaining contractual maturities for available-for-sale securities were one month to fifteen months. The unrealized losses for securities in an unrealized loss position for more than 12 months as of September 30, 2025, and December 31, 2024 were immaterial. For the three and nine months ended September 30, 2025 and 2024, the Company did not recognize credit loss related to available-for-sale debt securities.

5. Balance Sheet Components

Accounts Receivable

The following table presents the activities in the Company's allowance for credit losses (in thousands):

Balance as of December 31, 2024	\$ 2,577
Increase in allowance	1,622
Write-offs	(972)
Balance as of September 30, 2025	<u>\$ 3,227</u>

Inventories

Inventories consist of the following (in thousands):

	September 30, 2025	December 31, 2024
Raw materials	\$ 26,025	\$ 25,703
Work in process	7,478	9,973
Finished goods	15,786	23,711
Total inventories	<u>\$ 49,289</u>	<u>\$ 59,387</u>

Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following (in thousands):

	September 30, 2025	December 31, 2024
Inventory	\$ 1,615	\$ 2,079
Research and development expenses	56	219
Professional services	646	1,084
Customer rebates	818	1,733
Other	3,557	3,090
Total accrued expenses and other current liabilities	<u>\$ 6,692</u>	<u>\$ 8,205</u>

6. Commitments and Contingencies

Litigation

On August 29, 2024, a purported stockholder class action lawsuit (the Porcelli Complaint), Porcelli v. Outset Medical, Inc., et al., 5:24-cv-06124-EJD, was filed in the U.S. District Court for the Northern District of California, against the Company, its Chief Executive Officer, and then-Chief Financial Officer. On October 18, 2024, a second purported stockholder class action lawsuit (the Plymouth Complaint; together with the Porcelli Complaint, the Class Actions), Plymouth County Retirement Association v. Outset Medical, Inc., et al., 5:24-cv-06124-HSG, was filed in the same court. The second lawsuit also named the Company's prior Chief Financial Officer as a defendant (together with the CEO and then-CFO, the Class Defendants). The Porcelli Complaint alleged that, between August 1, 2022 and August 7, 2024, defendants made materially false or misleading statements in violation of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (Exchange Act) regarding the Company's business, operations, and prospects related to the sale and marketing of the Tablo Hemodialysis System and TabloCart with Prefiltration, including concerning the impact of certain FDA processes for these products on the Company's revenue growth. The Plymouth Complaint alleged similar violations between September 15, 2020 and August 7, 2024. On March 18, 2025, the court consolidated the Class Actions into one action captioned *In re Outset Medical, Inc. Securities Litigation*, Case No. 5:24-cv-06124-EJD, appointing a Lead Plaintiff and Lead Counsel. The Lead Plaintiff filed its consolidated amended complaint on June 6, 2025. The Class Defendants filed a motion to dismiss the consolidated amended complaint on August 14, 2025, and the Lead Plaintiff filed its opposition on October 6, 2025. The Class

Defendants' deadline to file their reply in support of the motion to dismiss is November 17, 2025. A hearing on the Class Defendants' motion to dismiss has been set for January 22, 2026.

On November 29, 2024, an Outset stockholder purporting to act on behalf of the Company filed an action in the U.S. District Court for the Northern District of California against current and former members of Outset's Board of Directors and certain of its officers (the Derivative Defendants), alleging that the Derivative Defendants breached their fiduciary duties to the Company in connection with the same alleged events and alleged materially false and misleading statements asserted in the Class Actions described above. Three additional substantively duplicative actions were filed in the U.S. District Court for the Northern District of California on April 28, 2025, May 8, 2025, and June 16, 2025. The complaints seek unspecified monetary damages and other relief. On July 17, 2025, the court entered a stay of all derivative actions pending the outcome of the Class Defendants' motion to dismiss the consolidated amended complaint.

The cases are at a very early stage and the Company cannot currently estimate the loss or the range of possible losses it may experience in connection with this litigation.

In addition, from time to time, the Company may become involved in other legal proceedings or investigations, which could have an adverse impact on its reputation, business and financial condition and divert the attention of the Company's management from the operation of the Company's business.

Indemnification

In the ordinary course of business, the Company often includes standard indemnification provisions in its arrangements with its partners, customers and suppliers. Pursuant to these provisions, the Company may be obligated to indemnify such parties for losses or claims suffered or incurred in connection with its service, breach of representations or covenants, intellectual property infringement or other claims made against such parties. These provisions may limit the time within which an indemnification claim can be made. It is not possible to determine the maximum potential amount under these indemnification obligations due to the limited history of prior indemnification claims and the unique facts and circumstances involved in each particular agreement. To date, the Company has not incurred any material costs as a result of such indemnification obligations and has not accrued any liabilities related to such obligations in these financial statements.

7. Term Loans

Term loans consist of the following (in thousands):

	September 30, 2025	December 31, 2024
Principal of term loans	\$ 101,114	\$ 200,000
Unamortized debt discount	(5,590)	(2,625)
Term loans, noncurrent	<u>\$ 95,524</u>	<u>\$ 197,375</u>

SLR Credit Facilities

In November 2022, the Company entered into two senior secured credit facilities, which collectively provide for borrowings of up to \$300.0 million as follows: (i) up to a \$250.0 million term loan facility pursuant to a loan and security agreement (the SLR Loan Agreement) among SLR Investment Corp., as collateral agent (SLR Agent), the lenders from time to time party thereto (the Term Loan Lenders) and the Company (the SLR Term Loan Facility), and (ii) up to a \$50.0 million asset-based revolving credit facility pursuant to a credit agreement (the SLR Revolving Credit Agreement, together with the SLR Loan Agreement, the SLR Credit Facility Agreements) among Gemino Healthcare Finance, LLC d/b/a SLR Healthcare ABL, as lender (ABL Lender), and the Company (the SLR Revolver, together with the SLR Term Loan Facility, the SLR Credit Facilities).

As of December 31, 2024, \$200.0 million was outstanding under the SLR Term Loan Facility and no amounts were outstanding under the SLR Revolver. On January 3, 2025, the Company terminated the SLR Credit Facility Agreements and repaid in full all amounts due, including a final payment of \$7.5 million and a termination fee of \$0.1 million, using the proceeds from the Perceptive Term Loan as described below, together with cash on hand. The repayment of the SLR Credit Facilities was accounted for as a debt extinguishment, which resulted in a loss on extinguishment of \$7.7 million recorded in the accompanying condensed statements of operations for the nine months ended September 30, 2025.

Perceptive Term Loan

On January 3, 2025, the Company entered into a senior secured credit facility for borrowings up to an aggregate principal amount of \$125.0 million pursuant to the Perceptive Credit Agreement with Perceptive Credit Holdings IV, LP (who also participated in the Private Placement). Pursuant to the terms and conditions of the Perceptive Credit Agreement, the lenders agreed to extend term loans to the Company in an aggregate principal amount of up to \$125.0 million, comprised of (i) a term loan of \$100.0 million (the

Initial Term Loan), which was funded on January 8, 2025 (the Closing Date), and (ii) a delayed draw term loan of up to \$25.0 million (the Delayed Draw Loan). The Initial Term Loan and the Delayed Draw Loan are referred to collectively as the Perceptive Term Loans. The Delayed Draw Loan is available for funding until July 14, 2027, subject to the achievement of a specific revenue milestone and other customary conditions.

The principal amount outstanding under the Loans will accrue interest at a rate per annum equal to (i) the greater of (a) one-month term SOFR or (b) 4.00% per annum, plus (ii) an applicable margin of 8.00%, payable monthly in arrears. During the first two years after the Closing Date, a portion of the accrued interest equal to 1.50% per annum will be paid in kind and added to the principal amount of the Loans on each monthly interest payment date. The outstanding principal amount of the Loans will be due and payable on the five year anniversary of the Closing Date (the Maturity Date).

The Company paid the lenders a non-refundable closing fee in the amount of \$1.0 million in respect of the Initial Term Loan on the Closing Date. The Company is obligated to pay the lenders a non-refundable closing fee in the amount of \$250,000 in respect of the Delayed Draw Loan, to be due and payable upon the funding of the Delayed Draw Loan.

On the Closing Date, the Company issued to Perceptive Credit Holdings IV, LP as the initial lender a warrant to purchase 375,000 of shares of the Company's common stock (the Closing Date Warrant), at an exercise price equal to \$12.00 per share. If the Company draws the Delayed Draw Loan, the Company is required to issue additional warrant(s) to the lenders to purchase 94,000 shares of the Company's common stock (the Delayed Draw Warrant), at an exercise price equal to the average closing price of the Company's common stock for the 5 trading days immediately preceding the issuance date of the Delayed Draw Warrant. Both the Closing Date Warrant and the Delayed Draw Warrant, if issued, are exercisable during the seven years after the date of issuance.

The fair value of the Closing Date Warrant of \$4.4 million and the debt issuance costs paid directly to Perceptive Credit Holdings IV, LP along with other debt issuance costs amounting to \$6.5 million were accounted for as a direct deduction from the term loan balance on the balance sheets and are being recognized as non-cash interest expense over the term of the loan using the effective interest method.

The Company may voluntarily prepay the outstanding loan(s), subject to a prepayment premium of (i) 10.0% of the principal amount of the prepaid loan(s), if prepaid prior to or on the first anniversary of the Closing Date, (ii) 8.0% of the principal amount of the prepaid Loans, if prepaid after the first anniversary of the Closing Date through and including the second anniversary of the Closing Date, (iii) 4.0% of the principal amount of the prepaid loan(s), if prepaid after the second anniversary of the Closing Date through and including the third anniversary of the Closing Date, (iv) 2.0% of the principal amount of the prepaid Loans, if prepaid after the third anniversary of the Closing Date through and including the fourth anniversary of the Closing Date, and (v) 0.00% of the principal amount of the prepaid loan(s), if prepaid after the fourth anniversary of the Closing Date.

The Perceptive Credit Agreement contains customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting and insurance and restrictions on the Company's ability to dispose of its business or property, to change its line of business, to liquidate or dissolve, to enter into any change in control transaction, to merge or consolidate with any other entity or to acquire all or substantially all the capital stock or property of another entity, to incur additional indebtedness, to incur liens on its property or to pay any dividends or other distributions on capital stock, in each case with certain exceptions. The Company has also agreed to certain financial covenants that require the Company to (i) maintain a minimum cash balance of at least \$10.0 million in accounts subject to control agreements in favor of Agent, and (ii) achieve certain trailing twelve-month net revenue targets as set forth in the Perceptive Credit Agreement.

In addition, the Perceptive Credit Agreement contains customary events of default that entitle the Agent to cause the Company's indebtedness under the Perceptive Credit Agreement to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the obligations owed under the Perceptive Credit Agreement. Under the Perceptive Credit Agreement, an event of default will occur if, among other things, the Company fails to make payments under the Perceptive Credit Agreement, the Company breaches certain covenants under the Perceptive Credit Agreement, subject to specified cure periods with respect to certain breaches, a material adverse change or a material regulatory event has occurred under the Perceptive Credit Agreement, or the Company or its assets become subject to certain legal proceedings, such as bankruptcy proceedings. Upon the occurrence and for the duration of an event of default, an additional default interest rate equal to 4.0% per annum will apply to all obligations owed under the Perceptive Credit Agreement.

8. Convertible Preferred Stock and Stockholders' Equity

Convertible Preferred Stock

The Company is authorized to issue a total of 5,000,000 shares of preferred stock, par value \$0.001 per share. In connection with the Private Placement described below, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series A Convertible Preferred Stock with the Delaware Secretary of State on January 7, 2025 (the Certificate of Designation) to set forth the preferences, rights and limitations of the Series A Convertible Preferred Stock. The Company has designated a total of 863,000 shares as Series A Convertible Preferred Stock, which are non-voting and not redeemable.

On January 3, 2025, the Company entered into securities purchase agreements with various investors, including certain of the Company's directors, officers and employees (the Investors) for the issuance and sale by the Company of an aggregate of 863,000 shares of Series A Convertible Preferred Stock, par value \$0.001 per share, at a purchase price of \$200.00 per share in the Private Placement. The sale of 844,000 shares of Series A Convertible Preferred Stock to institutional investors closed on January 8, 2025, with gross proceeds, before deducting placement agent fees and other offering expenses, of \$168.8 million. On March 7, 2025, following stockholder approval of the Company's issuance of shares of Series A Convertible Preferred Stock and shares of the Company's common stock issuable upon the conversion thereof to certain of the Company's directors, officers and employees at the special meeting of stockholders held on March 5, 2025 (the Special Meeting), the Company issued 19,000 shares of Series A Convertible Preferred Stock to certain of the Company's directors, officers and employees, with gross proceeds, before deducting offering expenses, of \$3.9 million.

On March 10, 2025, following the stockholder approval of the Company's issuance of common stock in excess of 20% of the Company's then outstanding shares of common stock at the Special Meeting, 842,000 shares of Series A Convertible Preferred Stock were converted into 14,046,000 shares of the Company's common stock at the conversion price of \$12.00 per share in accordance with the Certificate of Designation. Following the conversion, 21,000 shares of the Series A Convertible Preferred Stock remain issued and outstanding as of September 30, 2025. These remaining shares were subsequently converted into the Company's common stock in October 2025 (see Note 15 below).

In the event of any voluntary or involuntary liquidation, dissolution or winding-up of the Company, the Series A Convertible Preferred Stock shall rank on parity with the common stock as to distributions of assets. Series A Convertible Preferred Stock holders shall be entitled to receive, and the Company shall pay, dividends on shares of the Series A Convertible Preferred Stock (on an as-if-converted-to-Common-Stock basis) equal to and in the same form, and in the same manner, as dividends actually paid on shares of the common stock when, as and if such dividends (other than dividends payable in the form of common stock) are paid on shares of the common stock.

Based on the attributes of the Series A Convertible Preferred Stock as described above, the Company has accounted for the Series A Convertible Preferred Stock as a component of permanent stockholders' equity.

Common Stock Warrants

As discussed in Note 7 above, the Company issued a warrant to Perceptive Credit Holdings IV, LP to purchase 375,000 shares of the Company's common stock, at an exercise price equal to \$12.00 per share, in January 2025. This warrant is immediately exercisable upon issuance, and expires seven years after the date of issuance, January 2032. This warrant is outstanding and exercisable, and classified as a component of permanent stockholders' equity. The Company determined the fair value using the Black-Scholes option pricing model with the following assumptions on the date of issuance: common stock price of \$14.66 per share, expected volatility of 93%, expected term of 7 years, and risk-free interest rate of 4.56%.

9. Equity Incentive Plan

Equity Incentive Plan

At the Company's annual meeting of stockholders held on June 2, 2025 (the 2025 Annual Meeting), the Company's stockholders approved an amendment to the Company's 2020 Equity Incentive Plan (2020 Plan) to increase the number of shares of common stock available for issuance under the plan by 1,950,000 shares. As of September 30, 2025, 1,376,000 shares were reserved for future issuance under the 2020 Plan.

Employee Share Purchase Plan (ESPP)

At the 2025 Annual Meeting, the Company's stockholders approved an amendment to the Company's ESPP to increase the number of shares of common stock available for issuance under the plan by 255,000 shares. As of September 30, 2025, 248,000 shares of common stock were reserved for issuance in connection with the current and future offering periods under the ESPP.

Restricted Stock

The Company issues restricted stock units (RSUs) and performance stock units (PSUs), both of which are considered restricted stock. The Company grants restricted stock pursuant to the 2020 Plan and satisfies such grants through the issuance of new shares. RSUs are share awards that, upon vesting, will deliver to the holder shares of the Company's common stock.

RSUs with a service-based vesting condition granted to a grantee, beginning in February 2022, generally vest over a three-year period as follows: (i) 25% on the first anniversary of the vesting commencement date, 25% quarterly over the course of the second year, and 50% quarterly over the course of the third year, or (ii) 33% on the first anniversary of the vesting commencement date, with the balance vesting quarterly over the remaining two years.

Annual RSUs granted to non-executive employees in 2025 vest over one year with 100% vesting on the first anniversary of the grant date while the annual RSUs granted to executives in 2025 vest over a two-year period with 50% vesting on the first anniversary of the vesting commencement date, and the remaining 50% vesting quarterly over the following year.

Annual RSUs granted to non-executive employees in 2024 vest over a two-year period at a rate of 50% on the first anniversary of the original vesting date, with the balance vesting quarterly over the remaining one year.

Prior to February 2022, RSUs with a service-based vesting condition granted to a grantee generally vest at a rate of 25% on the first anniversary of the original vesting date, with the balance vesting quarterly over the remaining three years.

Since 2022, the Company has granted a mix of 50% PSUs and 50% RSUs to its CEO, and a mix of 20% PSUs and 80% RSUs to its other executive officers and certain other senior leaders on an annual basis. These PSUs are earned and vest based on achievement against a performance-based metric and a market-based metric as follows:

- Performance-based vesting conditions:
 - o PSUs granted in 2022 through 2024 are earned based on the number of patients treating at home on Tablo as of the end of the second or third year following the grant date (Year 2 or Year 3), with earned units vesting either (i) 50% after certification of achievement following the end of Year 2 and 50% at the end of Year 3 or (ii) 100% after certification of achievement following the end of Year 3 (Home PSUs); or
 - o PSUs granted in 2025 are earned based on the Company's three-year non-GAAP cumulative earnings before income tax, depreciation and amortization (EBITDA) at the end of 2027, with 100% of earned units vesting after certification of the achievement level following the end of 2027 (EBITDA PSUs).
- Market-based vesting conditions:
 - o PSUs granted in 2022 through 2025 are earned based on the Company's relative total stockholder return (Relative TSR) at the end of a two-year or three-year performance period as compared to companies in a pre-determined index of medical device companies, in each case, with 100% of earned units vesting at the end of Year 3, or after certification of achievement following the end of the three-year performance period (Relative TSR PSUs).

The number of units earned varies based on actual performance as follows: (i) from 0% to 200% (250% for the CEO) of the target number of the Home PSUs and EBITDA PSUs granted, (ii) from 75% to 150% (250% for the CEO) of the target number of Relative TSR PSUs granted in 2022 and 2023 and (iii) from 0% to 200% (250% for the CEO) of the target number of Relative TSR PSUs granted in 2024 and 2025.

The grant dates for the Home PSUs and EBITDA PSUs are not considered established until the Compensation Committee of the Board approves the target and it is communicated to the award recipients, which then triggers the service inception date, the fair value of the awards, and the associated expense recognition period. Once the grant dates for the Home PSUs and EBITDA PSUs have been established, the related stock-based compensation expense would be recorded based on the forecasted performance, which is reassessed each reporting period based on the probability of achieving the performance conditions.

In 2024, the Company also granted a new type of PSU award to executive officers and certain other senior leaders which is earned and vests based on appreciation of the Company's stock price above pre-determined stock price triggers or achievement of specified non-GAAP operating income targets over a performance period of up to three years.

Stock-Based Compensation Expense

The following table sets forth stock-based compensation expense included in the accompanying condensed statements of operations (in thousands):

	Three Months Ended		Nine Months Ended	
	September 30,		September 30,	
	2025	2024	2025	2024
Cost of revenue	\$ 135	\$ 296	\$ 438	\$ 1,092
Research and development	1,117	1,400	2,426	6,025
Sales and marketing	1,174	945	2,586	4,898
General and administrative	2,654	3,747	6,103	12,396
Total stock-based compensation expense	\$ 5,080	\$ 6,388	\$ 11,553	\$ 24,411

10. Income Taxes

For each of the three and nine months ended September 30, 2025 and 2024, the Company incurred an income tax provision of an insignificant amount, which related to foreign income taxes for the Company's Mexico operations. The U.S. federal and state net

deferred tax assets have been fully offset by a valuation allowance, as the Company believes it is not more likely than not that the deferred tax assets will be realized.

11. Net Loss Per Share

The following outstanding potentially dilutive shares were excluded from the calculation of diluted net loss per share due to their anti-dilutive effect (in thousands):

	Three and Nine Months Ended September 30,	
	2025	2024
Stock options to purchase common stock	82	101
Restricted stock units	762	264
Performance stock units	7	18
Shares committed under ESPP	9	21
Series A Convertible Preferred Stock	343	—
Warrants to purchase common stock	375	4
Total	1,578	408

12. Segment

The key measure of segment profit or loss that the Company's chief operating decision maker (CODM), its Chief Executive Officer, uses to allocate resources and assess performance is the Company's net loss, as reported on the accompanying condensed statements of operations. Net income is used to monitor budget versus actual results.

There are no intra-entity sales or transfers. All expense categories on the accompanying condensed statements of operations are significant and there are no other expense categories regularly provided to the CODM beyond those disclosed in the accompanying condensed statements of operations. The CODM manages the business using expense information as well as regularly provided budgeted or forecasted expense information for the single operating segment. The measure of segment assets is reported on the accompanying condensed balance sheets as total consolidated assets with particular emphasis on the Company's available liquidity, including its cash, cash equivalents, restricted cash, and short-term investments.

13. Workforce Reduction

In order to improve operational efficiencies, reduce operating expenses and streamline its overall organizational structure, the Company implemented two organizational restructuring plans to reduce its workforce in the fourth quarter of 2023 and May 2024 and incurred restructuring charges of \$2.5 million in fiscal year 2023 and \$2.7 million through the first half of fiscal year 2024 for employee severance and other termination benefits.

In connection with steps the Company took to help optimize its commercial organization, and to help improve operational efficiencies and reduce operating expenses to align with anticipated revenue growth, in the third quarter of 2024, the Company completed an additional restructuring plan primarily impacting its commercial organization. The Company incurred restructuring charges of \$1.4 million in the third quarter of 2024 for employee severance and other termination benefits associated with this restructuring.

In January 2025, the Company implemented another restructuring plan and, as a result, estimated and recognized restructuring charges of \$1.5 million as of December 31, 2024 for employee severance and other termination benefits. Restructuring accruals were based upon management estimates at the time and adjusted based on the changes in facts and circumstances subsequent to the date the original liability was recorded.

The following table sets forth severance and related benefits charges included in the accompanying condensed statements of operations (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Cost of revenue	\$ —	\$ 530
Research and development	34	1,260
Sales and marketing	—	1,884
General and administrative	(42)	475
Total	\$ (8)	\$ 4,149

For the nine months ended September 30, 2025, changes in liabilities resulting from the restructuring accruals, which were recorded in accrued compensation and related benefits on the accompanying condensed balance sheet, were as follows (in thousands):

Balance as of December 31, 2024	\$	1,501
Charges		34
Payments and other adjustments		(1,535)
Balance as of September 30, 2025	\$	<u>—</u>

14. Related Party Transactions

As discussed in Note 8, certain of the Company's directors, officers and employees purchased 19,000 shares of Series A Convertible Preferred Stock for a total purchase price of \$3.9 million in March 2025. These shares of Series A Convertible Preferred Stock were subsequently converted to common stock.

15. Subsequent Event

In October 2025, the remaining 21,000 shares of the Series A Convertible Preferred Stock were converted into 343,000 shares of the Company's common stock in accordance with the Certification of Designation.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes and other financial information included elsewhere in this Quarterly Report, as well as our audited financial statements and notes thereto and the related Management’s Discussion and Analysis of Financial Condition and Results of Operations included in our 2024 Annual Report. As used in this Quarterly Report, references to the “Company,” “we,” “us,” “our,” or similar terms refer to Outset Medical, Inc.

In addition to historical financial information, this discussion and other parts of this report contain forward-looking statements within the meaning of the federal securities laws. All statements other than statements of historical fact contained in this Quarterly Report are forward-looking statements. In some cases, you can identify these statements by forward-looking words such as “believe,” “may,” “will,” “estimate,” “continue,” “anticipate,” “intend,” “could,” “would,” “project,” “predict,” “plan,” “expect” or the negative or plural of these words or similar expressions. The forward-looking statements in this report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Such risks and uncertainties include those described throughout this Quarterly Report, including in this discussion as well as in the section titled “Risk Factors” under Part II, Item 1A below and in Part I, Item 1A, “Risk Factors” and in Part II, Item 7, “Management’s Discussion and Analysis of Financial Condition and Results of Operations” in our 2024 Annual Report. The forward-looking statements in this Quarterly Report are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements, like all statements in this report, speak only as of their date, and, except as required by law we undertake no obligation to update or revise these statements, whether as a result of any new information, future developments or otherwise. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.

Overview

Our technology is designed to elevate the dialysis experience for patients and help providers overcome traditional care delivery challenges. Requiring only an electrical outlet and tap water to operate, our Tablo® Hemodialysis System (Tablo) frees patients and providers from the burdensome infrastructure required to operate traditional dialysis machines. The integration of water purification and on-demand dialysate production in a single 35-inch compact console enables Tablo to serve as a dialysis clinic on wheels. With a simple-to-use touchscreen interface, two-way wireless data transmission and a proprietary data analytics platform, Tablo is a holistic approach to dialysis care. Unlike existing hemodialysis machines, which have limited clinical versatility across care settings, Tablo can be used seamlessly across multiple care settings and a wide range of clinical applications. Tablo is cleared by the FDA for use in the hospital, clinic, or home setting.

Tablo leverages cloud technology, making it possible for providers to monitor devices remotely, view treatment data, perform patient and population analytics, and automate clinical recordkeeping. Tablo’s wireless connectivity enables us to release training, new features and enhancements over-the-air without interventions by field service engineers. Tablo’s connectedness allows continuous streaming of over 500,000 device performance data points to the cloud for every treatment. We use this data, in conjunction with our diagnostic and predictive algorithms, to monitor device performance, identify and diagnose failures and, in some instances, predict and prevent potential future device failures or malfunctions. In effect, this contributes to a reduction in service hours and an increase in device uptime.

We have generated meaningful evidence to demonstrate that providers can realize significant operational efficiencies, including reducing the cost of their dialysis programs. In addition, Tablo has been shown to deliver robust clinical care. In studies and surveys we have conducted, patients have reported quality of life benefits on Tablo compared to other dialysis machines. We believe Tablo empowers patients, who have traditionally been passive recipients of care, to regain agency and ownership of their treatment.

Driving adoption of Tablo in the acute care setting has been our primary focus to date. We have invested in growing our economic and clinical evidence, built a veteran sales and clinical support team with significant expertise, and implemented a comprehensive training and customer experience program. Our experience in the acute care market has demonstrated Tablo’s clinical flexibility and operational versatility, while also delivering meaningful cost savings to the providers. In addition, we are also working with skilled nursing facilities (SNFs), sub-acute long-term acute care hospitals (LTACHs), and other post-acute providers to raise awareness of Tablo’s economic and clinical benefits to them and to patients. We plan to continue leveraging our commercial infrastructure to broaden our installed base in the acute and post-acute care markets, as well as driving utilization and fleet expansion with our existing customers.

Tablo is also utilized for home-based dialysis. We believe our ability to reduce training time, patient dropout, and the supplies and infrastructure required to deliver dialysis in the home can drive efficiency and economic improvements to the home care model. In our home investigational device exemption trial, patients reported specific quality of life improvements compared to their experience on the incumbent home dialysis machine. To penetrate this market successfully, we have made investments in and continue to focus on refining our home distribution, logistics and support systems to help ensure they are ready for scale. We are also working with providers, patients, and payors to increase awareness and adoption of transitional care units as a bridge to home-based therapy.

We generate revenue from the placement of Tablo consoles along with accessories, and shipping and handling charged to customers, which revenue is recognized up-front. We also earn recurring revenue from sales of consumables, including Tablo cartridge, and services, which generates significant total revenue over the life of Tablo consoles. Our total revenues were \$29.4 million and \$28.7 million for the three months ended September 30, 2025 and 2024, respectively, and \$90.6 million and \$84.2 million for the nine months ended September 30, 2025 and 2024, respectively.

We primarily sell our solutions through our direct sales organization, which covers most major metropolitan markets in the United States. Our sales organization is comprised of our capital sales team, responsible for generating new customer demand for Tablo, and our clinical sales team, responsible for driving utilization and fleet expansion of Tablo at existing customer sites. In addition, our field service team provides maintenance services and product support to our customers. Our field sales and service teams represent 56% of our total full-time employees as of September 30, 2025. The same sales organization and field service team drive Tablo penetration in both the acute and home markets. We believe the ability to leverage one team to serve both markets will result in significant productivity and cost optimization as we continue to scale our business.

Key Factors Affecting Our Performance

We believe that our financial performance has been, and in the foreseeable future will continue to be, primarily driven by the following factors. While we believe each of these factors presents significant opportunities for our business, they also pose important challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described in the section titled “Risk Factors.”

Market Acceptance of Tablo in Acute Setting

We plan to further broaden our installed base by continuing to target national and regional integrated delivery networks and health systems, SNFs, LTACHs and other post-acute providers. In addition, we focus on driving utilization and fleet expansion with existing customers by providing an exceptional user experience delivered through our commercial team and a steady release of software enhancements that amplify Tablo’s operational reliability and clinical versatility. Our ability to successfully execute on this strategy, and thereby increase our revenue in the acute market, will depend on several factors. These factors include our ability to recover from the adverse impact in the field from the warning letter we received from the FDA in July 2023 as we resume distribution of TabloCart with Prefiltration, as well as the success of our initiatives to optimize and further evolve our commercial organization, infrastructure and sales processes to support the growth of our business in the acute and post-acute care markets as we focus more heavily on enterprise selling and transition beyond earlier stage adoption of Tablo.

Expansion of Tablo within the Home Setting

We believe that a significant growth opportunity exists within the home hemodialysis market. We are partnering with innovative dialysis clinic providers, health systems and other adjacent healthcare providers who are motivated to grow their home hemodialysis population, and who share our vision of creating a seamless and supported transition to the home. We are also investing in market development over the longer term to expand the home hemodialysis market itself. The expansion of the home hemodialysis market and our ability to penetrate this market will be an important factor in driving the future growth of our business. In addition, the success of our efforts to expand within the home market, help grow new home programs and increase our revenue generated from home-based dialysis on the timeline that we anticipate will depend on several factors. These factors include the success of our initiatives to optimize and further evolve our commercial organization, infrastructure and sales processes as we scale our business in the home market.

Gross Margin

Our ability to expand our gross margins depends on: first, our ability to continue to sell Tablo cartridges, services, and accessories for Tablo consoles; second, our ability to reduce the cost of service and third, our ability to reduce the cost to manufacture Tablo consoles. Our ability to expand gross margins will also depend in part on our ability to control the average selling prices of our products and services, including by selling higher-margin accessories, consumables and services. Further, we will continue to utilize our cloud-based data system, as well as enhanced product and support performance, to improve service margin and drive down service costs per console. In addition, over the past several years, we have moved the production of Tablo consoles and a majority of Tablo cartridges in-house to our manufacturing facility in Tijuana, Mexico which we operate in collaboration with TACNA, as part of our cost reduction activities. This has helped further our long-term gross margin expansion and supply continuity strategies while reducing

the costs of Tablo console production and improving the flexibility of our operations. We will continue our cost reduction activities by using our design, engineering, supply chain and manufacturing capabilities to help further advance and improve the efficiency of our manufacturing processes, lowering the cost of parts and components and lowering our costs of production. Our ability to expand gross margins depends on our ability to successfully execute these strategies, as well as the impact of macroeconomic factors described below, including the tariffs imposed by the current administration.

Profitability Initiatives

Our ability to achieve and sustain profitability depends on several key factors: first, our ability to grow our revenue while expanding gross margins, as discussed above; second, our ability to optimize operating expenses; and third, our ability to optimize working capital. We have undertaken various initiatives designed to improve operational efficiencies, reduce operating expenses to align with anticipated levels of revenue growth and streamline our overall cost structure, including several organizational restructurings implemented beginning in the fourth quarter of 2023 through early 2025. We are also taking steps to improve our ability to efficiently manage working capital, including inventory. Our ability to transition to profitability will depend on the success of our efforts to optimize spending and working capital, including inventory.

Impacts of Macroeconomic Factors

Global macroeconomic conditions, including inflationary pressures, rising interest rates, changes in tariff or trade laws and policies (such as the tariffs imposed by the current administration), increased labor costs, staffing shortages and global supply chain disruptions, may impact our business and results of operations, and those of our customers, manufacturing partners and suppliers. As the duration and severity of these macroeconomic conditions remain uncertain and depend on various factors, we cannot predict what effects these macroeconomic conditions will ultimately have on our business and results of operations, our customers, or our suppliers.

Beginning in the third quarter of 2023, we began to observe an increasing number of our existing and prospective customers deferring their decisions to purchase Tablo in an environment of rising interest rates and more cautious capital spending. These deferrals served to elongate our sales cycle and the timing of delivery and installations, which, in turn, contributed to an adverse impact on our bookings and revenues starting in the second half of 2023 and through 2024. We may see disruption from this in future periods. In addition, ongoing uncertainty relating to various policy changes under the current administration – including developments in trade policy (such as increased tariffs), changes in interest rate policy, potential reductions in government reimbursement and shifts in broader healthcare policy – could increase financial pressures faced by our existing and prospective hospital customers. These actual or anticipated policy changes may lead to higher operating costs for our customers, as well as tighter operating budgets and more cautious capital spending decisions. Additionally, broader economic uncertainty and market volatility – driven in part by these evolving policies – could exacerbate financial strain on our customers, potentially resulting in delayed or reduced purchases of our products and services. These factors could adversely impact our revenues, results of operations and financial condition in future periods.

If our customers continue to face prolonged periods of rising interest rates, capital budget constraints, volatility, uncertainty, staffing shortages, cash flow challenges, rising costs and other financial pressures, whether due to general macroeconomic conditions, evolving policy changes under the current administration (including trade policy developments, reductions in government reimbursement or shifts in healthcare policy), cybersecurity events or other factors, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, timely collect amounts due, effectively manage our inventory levels, and have a material adverse effect on our bookings, revenues, results of operations, financial condition, and, ultimately, our future growth and profitability.

From a supply chain perspective, we have worked closely with our manufacturing partners and suppliers to enable us to source key components and maintain appropriate inventory levels to meet customer demand, and have not experienced material disruptions in our supply chain to date. However, macroeconomic factors such as rising inflation, increasing labor costs, and surges and shifts in consumer demand have disrupted the operations of certain of our third-party suppliers, resulting, in some cases, in increased lead times and higher component costs. We believe that localizing production of a majority of Tablo cartridges in Mexico (in-house at our manufacturing facility) has helped achieve cost reductions through lower freight costs, further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations. However, we may face increased supply chain constraints in the future, which could negatively impact our ability to meet customer demand on a timely basis, result in customer dissatisfaction and adversely impact our operating margins and results of operations. Moreover, increased tariffs imposed by the current administration, including on goods imported into the United States from Mexico and China, could adversely impact our supply chain and distribution costs, as well as our ability to achieve sustainable gross margins. We currently do not believe we have exposure to these tariffs as Tablo, TabloCart and Tablo cartridge are covered under a special exemption. However, in September 2025, the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 to assess the national security implications of imports of personal protective equipment, medical consumables, and medical equipment, including medical devices. The outcome of this investigation could result in additional tariffs or other trade restrictions. While we continue to believe our products will remain exempt, the scope and outcome of the investigation are uncertain and could affect existing exemptions or expand coverage to additional product categories. We cannot predict what actions may ultimately be taken with respect to tariffs or trade

relations between the United States and other countries (including Mexico and China), what products may be subject to such actions, or what actions may be taken by the other countries in retaliation.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2025 and 2024 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Revenue:				
Product revenue	\$ 20,558	\$ 20,305	\$ 64,934	\$ 59,971
Service and other revenue	8,873	8,361	25,668	24,251
Total revenue	29,431	28,666	90,602	84,222
Cost of revenue:				
Cost of product revenue	11,169	11,532	33,962	34,680
Cost of service and other revenue	6,672	7,314	22,117	21,725
Total cost of revenue	17,841	18,846	56,079	56,405
Gross profit	11,590	9,820	34,523	27,817
Operating expenses:				
Research and development	5,376	8,139	16,180	30,508
Sales and marketing	13,550	15,417	41,482	54,593
General and administrative	8,477	10,103	25,938	34,231
Total operating expenses	27,403	33,659	83,600	119,332
Loss from operations	(15,813)	(23,839)	(49,077)	(91,515)
Interest income and other income, net	1,855	2,149	5,734	7,718
Interest expense	(3,476)	(6,068)	(10,511)	(18,046)
Loss on extinguishment of term loan	—	—	(7,685)	—
Loss before provision for income taxes	(17,434)	(27,758)	(61,539)	(101,843)
Provision for income taxes	404	182	623	495
Net loss	<u>\$ (17,838)</u>	<u>\$ (27,940)</u>	<u>\$ (62,162)</u>	<u>\$ (102,338)</u>

Comparison of the Three and Nine Months Ended September 30, 2025 and 2024

Revenue

<i>(dollars in thousands)</i>	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2025	2024	\$	%	2025	2024	\$	%
	Revenue:							
Product revenue	\$ 20,558	\$ 20,305	\$ 253	1%	\$ 64,934	\$ 59,971	\$ 4,963	8%
Service and other revenue	8,873	8,361	512	6%	25,668	24,251	1,417	6%
Total revenue	<u>\$ 29,431</u>	<u>\$ 28,666</u>	765	3%	<u>\$ 90,602</u>	<u>\$ 84,222</u>	6,380	8%

Product revenue increased by \$0.3 million, or 1%, for the three months ended September 30, 2025 as compared to the same period in the prior year. This increase was driven by a \$0.6 million increase in console revenue, which was offset by a \$0.3 million decrease in consumable revenue.

Product revenue increased by \$5.0 million, or 8%, for the nine months ended September 30, 2025 as compared to the same period in the prior year. This increase was driven by a \$4.7 million increase in consumable revenue and a \$0.3 million increase in console revenue.

Service and other revenue increased for the three and nine months ended September 30, 2025 as compared to the same periods in the prior year. The increase was primarily due to services associated with growth in our console installed base.

Gross Profit and Gross Margin

<i>(dollars in thousands)</i>	Three Months Ended		Change		Nine Months Ended		Change	
	September 30,				September 30,			
	2025	2024	\$	%	2025	2024	\$	%
Gross profit and gross margin:								
Gross profit	\$ 11,590	\$ 9,820	\$ 1,770	18%	\$ 34,523	\$ 27,817	\$ 6,706	24%
Gross margin	39.4 %	34.3 %			38.1 %	33.0 %		

Gross profit increased for the three and nine months ended September 30, 2025 as compared to the same periods in the prior year. Gross margin improved by 5.1 percentage points for both the three and nine months ended September 30, 2025 as compared to the same periods in the prior year. These improvements in gross profit and gross margin were primarily driven by higher average selling prices for consumables and consoles and lower unit cost per console. Higher gross margin on service and other revenue also contributed to the improvements in gross profit and gross margin.

Operating Expenses

<i>(dollars in thousands)</i>	Three Months Ended		Change		Nine Months Ended		Change	
	September 30,				September 30,			
	2025	2024	\$	%	2025	2024	\$	%
Operating expenses:								
Research and development	\$ 5,376	\$ 8,139	\$ (2,763)	(34)%	\$ 16,180	\$ 30,508	\$ (14,328)	(47)%
Sales and marketing	13,550	15,417	(1,867)	(12)%	41,482	54,593	(13,111)	(24)%
General and administrative	8,477	10,103	(1,626)	(16)%	25,938	34,231	(8,293)	(24)%
Total operating expenses	\$ 27,403	\$ 33,659	(6,256)	(19)%	\$ 83,600	\$ 119,332	(35,732)	(30)%

Research and development expenses decreased for the three months ended September 30, 2025 as compared to the same period in the prior year. The decrease was primarily due to an overall decrease in compensation-related and stock-based compensation expense and infrastructure costs.

Research and development expenses decreased for the nine months ended September 30, 2025 as compared to the same period in the prior year. The decrease was primarily due to an overall decrease in compensation-related and stock-based compensation expense, consulting expense, and infrastructure costs.

Sales and marketing expenses decreased for the three months ended September 30, 2025 as compared to the same period in the prior year. The decrease was primarily driven by an overall decrease in compensation-related expense and infrastructure costs. This decrease was slightly offset by increases in freight and stock-based compensation expenses.

Sales and marketing expenses decreased for the nine months ended September 30, 2025 as compared to the same period in the prior year. The decrease was primarily driven by an overall decrease in compensation-related and stock-based compensation expense, travel expense and infrastructure costs.

General and administrative expenses decreased for the three months ended September 30, 2025 as compared to the same period in the prior year. The decrease was primarily due to an overall decrease in compensation-related and stock-based compensation expense.

General and administrative expenses decreased for the nine months ended September 30, 2025 as compared to the same period in the prior year. The decrease was primarily due to an overall decrease in compensation-related and stock-based compensation expense. The decrease was partially offset by the higher legal costs related to the stockholder class action and related derivative lawsuits.

Other Income (Expenses), Net

<i>(dollars in thousands)</i>	Three Months Ended		Change		Nine Months Ended		Change	
	September 30,				September 30,			
	2025	2024	\$	%	2025	2024	\$	%
Other income (expenses), net:								
Interest income and other income, net	\$ 1,855	\$ 2,149	\$ (294)	(14)%	\$ 5,734	\$ 7,718	\$ (1,984)	(26)%
Interest expense	(3,476)	(6,068)	2,592	(43)%	(10,511)	(18,046)	7,535	(42)%
Loss on extinguishment of term loan	—	—	—	—	(7,685)	—	(7,685)	*
Total other expenses, net	\$ (1,621)	\$ (3,919)	2,298	(59)%	\$ (12,462)	\$ (10,328)	(2,134)	21%

* Not meaningful

The decrease in interest income and other income, net for the three and nine months ended September 30, 2025 as compared to the same periods in the prior year were driven by a lower average short-term investment balance in 2025.

The decreases in interest expense for the three and nine months ended September 30, 2025 were primarily due to a lower outstanding term loan balance in 2025.

The loss on extinguishment of term loan of \$7.7 million was recognized for the repayment of the SLR Term Loan in 2025, which included final payment and termination fees.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have incurred net losses and negative cash flows from operations. To date, we have financed our operations and capital expenditures primarily through sales of equity securities, revenue from sales, debt financings, and proceeds from employee exercise of stock options and ESPP purchases.

As of September 30, 2025, we had cash, cash equivalents, restricted cash, and short-term investments of \$182.0 million. In January and March 2025, we sold 863,340 shares of Series A Convertible Preferred Stock at a price of \$200.00 per share in the Private Placement for total gross proceeds of \$172.7 million, before deducting placement agent fees and other offering expenses. Subsequently, 842,753 shares of Series A Convertible Preferred Stock were converted into 14,045,866 shares of our common stock in March 2025. The remaining 20,587 shares of Series A Convertible Preferred Stock were converted into 343,117 shares of our common stock in October 2025.

In addition, in January 2025, we entered into the Perceptive Credit Agreement with Perceptive Credit Holdings IV, LP, which provided a \$100 million 5-year term loan at closing and provides an additional term loan of up to \$25 million, which is available for funding until July 14, 2027, subject to achievement of a specified revenue milestone and other customary conditions.

We are required to comply with certain covenants under the Perceptive Credit Agreement, including, among others, requirements as to financial reporting, restrictions on our ability to incur additional indebtedness and to pay any dividends or other distributions on capital stock, maintenance of a minimum cash balance, and achievement of certain specified trailing twelve-month net revenue targets. If we fail to comply with any covenants, payments or other terms of the Perceptive Credit Agreement and such failure constitutes an event of default thereunder, such event of default would give Agent the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable.

While we have taken actions to reduce operating expenses and working capital to align with anticipated revenue growth including implementing restructuring plans to streamline our overall organizational structure and renegotiating commitments with suppliers to reduce inventory, we expect to continue to incur operating losses in the near term while we make investments to support our anticipated growth. We may raise additional capital through the issuance of additional equity financing, debt financings, which may require refinancing or amending the terms of our existing debt, or other sources. If this financing is not available to us at adequate levels or on acceptable terms, we may need to further evaluate our operating plans. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. We are subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional capital through debt financing (including through our existing debt), we may be subject to an increase in our interest expense which may negatively affect our cash flow.

We believe that our existing cash, cash equivalents and short-term investments, cash generated from sales, and proceeds received from the debt financing and the Private Placement described in Note 7 and 8, respectively, of the accompanying condensed financial statements above, will be sufficient to meet our anticipated needs for at least the next 12 months from the issuance date of this Quarterly Report.

Cash Flows Summary

The following table summarizes the cash flows for each of the periods indicated (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Net cash (used in) provided by:		
Operating activities	\$ (36,806)	\$ (99,815)
Investing activities	(106,274)	(4,215)
Financing activities	55,503	68,808
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (87,577)</u>	<u>\$ (35,222)</u>

Operating Activities

The net cash used in operating activities of \$36.8 million for the nine months ended September 30, 2025 was due to a net loss of \$62.2 million, the amortization of premiums on investments of \$1.7 million, and provision for inventories of \$0.2 million, which were adjusted by stock-based compensation expense of \$11.6 million, loss on extinguishment of term loan of \$7.7 million, depreciation and amortization of \$3.5 million, non-cash interest expense of \$2.0 million, non-cash lease expense of \$1.2 million, a net cash inflow from the change in our operating assets and liabilities of \$0.7 million, and provision for credit losses of \$0.7 million. The net cash inflow from operating assets and liabilities was primarily due to decreases in inventory, accounts receivable and prepaid expenses and other assets, and an increase in deferred revenue due to growth in our business. This net cash inflow from operating assets and liabilities was partially offset by a decrease in accrued compensation and related benefits resulting from the payouts of 2024 annual cash bonus, a decrease in accrued interest as a result of the termination of the SLR Term Loan, and decreases in accounts payable, operating lease liabilities, accrued expenses and accrued warranty liability.

Investing Activities

The net cash used in investing activities of \$106.3 million for the nine months ended September 30, 2025 was due to purchases of short-term investment securities of \$193.7 million and purchases of property and equipment of \$0.6 million, which was partially offset by the maturities of short-term investment securities of \$88.0 million.

Financing Activities

The net cash provided by financing activities of \$55.5 million for the nine months ended September 30, 2025 was due to net proceeds of \$161.5 million from the issuance of Series A Convertible Preferred Stock, net proceeds of \$98.3 million from borrowings under the Perceptive Term Loan Facility, and proceeds from ESPP purchases, partially offset by cash outflow of \$205.0 million in repayment of the SLR Term Loan which included final payment and termination fees.

Critical Accounting Estimates

Management's discussion and analysis of the financial condition and results of operations is based on the financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses incurred during the reporting periods. The estimates are based on historical experience and on various other factors that are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no new or significant changes in our critical accounting estimates as compared to the critical accounting estimates disclosed in Part II Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2024 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation and supervision of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to our management, including our Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of the end of the period covered by this Quarterly Report.

Changes in Internal Control over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) during our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

The information set forth under “Litigation” in Note 6, Commitments and Contingencies, of the notes accompanying our unaudited condensed financial statements in this Quarterly Report is incorporated herein by reference.

Item 1A. Risk Factors.

You should carefully consider the risk factors discussed in Part I, “Item 1A. Risk Factors” in our 2024 Annual Report, as updated by the risk factors discussed in Part II, “Item 1A. Risk Factors” in our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2025 (Q1 2025 Quarterly Report) and June 30, 2025 (Q2 2025 Quarterly Report), which could materially affect our business, financial position, or future results of operations. There have been no material changes to the risk factors described in our 2024 Annual Report, as updated by our Q1 2025 Quarterly Report and Q2 2025 Quarterly Report, except as set forth below. The risks described in our 2024 Annual Report and Q1 2025 Quarterly Report, as updated below, are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial, may also arise and materially impact our business. If any of these risks occur, our business, results of operations and financial condition could be materially and adversely affected and the trading price of our common stock could decline.

With a significant portion of our manufacturing operations located outside of the United States, we may experience manufacturing disruptions, and be subject to additional risks associated with international manufacturing operations, including uncertain or changing regulatory and/or labor requirements.

We have insourced the production of Tablo consoles, and a majority of Tablo cartridges, at our manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. Under our arrangement with TACNA, we control the operations, engineering, quality and materials supply functions at the facility, while TACNA provides manufacturing space, the workforce, utilities, cross-border logistics, local permits and licenses. We are subject to a number of additional risks associated with operating our Mexico-based manufacturing facility, and many of these risks may heighten to the extent we continue to ramp our cartridge manufacturing capabilities and increase our dependence on our Mexico-based manufacturing operations. We may experience strikes, work stoppages, work slowdowns, high personnel turnover, grievances, complaints, claims of unfair labor practices, other collective bargaining disputes or other labor disputes at our new facility. Our manufacturing operations at the facility may also suffer disruptions from global or regional public health crises such as the COVID-19 pandemic, natural disasters, cyber security attacks, vandalism, terrorism or other political hostilities. Any such occurrences could negatively impact our ability to produce Tablo consoles and cartridges.

We are also subject to a variety of foreign laws and regulations, including trade and labor restrictions and laws relating to importation, exportation and taxation of goods, and U.S. laws and regulations relating to foreign operations, including anti-corruption, anti-bribery and anti-money laundering laws. For example, the new administration has advocated greater restrictions on trade generally and, in particular, tariff increases on certain goods imported into the United States, including from Mexico and China. In February 2025, the current administration issued executive orders imposing additional 25% tariffs on products imported from Mexico and additional 10% tariffs on products imported from China. While the tariffs on products from China went into effect in February 2025 (and increased from 10% to 20% in March 2025), the tariffs on products from Mexico were suspended for an additional month. These tariffs could potentially impact certain areas of our supply chain, including raw materials entering Mexico, raw materials entering the United States from China for use by our United States-based suppliers, and finished goods imported from Mexico into the United States. We currently do not believe we have exposure to these tariffs as Tablo, TabloCart and Tablo cartridge are covered under a special exemption. However, in September 2025, the U.S. Department of Commerce initiated an investigation under Section 232 of the Trade Expansion Act of 1962 to assess the national security implications of imports of personal protective equipment, medical consumables, and medical equipment, including medical devices. The outcome of this investigation could result in additional tariffs or other trade restrictions. While we continue to believe our products will remain exempt, the scope and outcome of the investigation are uncertain and could affect existing exemptions or expand coverage to additional product categories. We cannot predict what actions may ultimately be taken with respect to tariffs or trade relations between the United States and other countries (including Mexico and China), which products may become subject to such actions, or how other countries may respond in retaliation. The adoption and expansion of trade restrictions, the occurrence of a trade war, other governmental action related to tariffs or trade agreements or policies, or the related uncertainties, has the potential to adversely impact our supply chain and distribution costs, which could in turn adversely affect our business, financial condition, and results of operations, including our ability to expand gross margins.

Furthermore, while proposals to amend Mexico’s federal labor law, including a reduction in maximum workweek hours from 48 to 40 hours, were rejected by the Mexican Congress in 2024, these initiatives remain a legislative priority. In 2025, the Mexican government publicly announced its intention to pursue this change through a phased implementation, with the goal of

reaching a 40-hour workweek by 2030, although the specific details, timing and scope of implementation remain under discussion. If enacted, these potential legislative changes are expected to increase our labor costs and, ultimately, could potentially negatively impact the productivity of our manufacturing operations to the extent our efforts to mitigate the impact of the changes are not successful. In addition, because certain of our Mexico-based manufacturing operations incur costs that are denominated in Mexican Pesos (MXN), we are exposed to additional risk of currency fluctuations between the U.S. dollars (USD) and MXN, which could increase our product and labor costs, thus reducing our gross profit. Moreover, while certain members of our management team have some manufacturing experience, as an organization, we do not have any prior experience in this type of manufacturing arrangement, and we could accordingly experience other risks, the nature and magnitude of which we are unable to assess precisely at this time. Furthermore, we are subject to increased risks related to changes in export or import regulation, other trade barriers, security measures and uncertainties impacting the cost and the ability to move inventory and manufacturing equipment across the United States-Mexico border. These risks may disrupt our Mexico-based manufacturing operations, subject us to increased costs, restrict or delay our ability to deliver products to our customers and meet our customers' demand on a timely basis, and result in customer dissatisfaction, all of which would adversely impact our results of operations.

In addition, we continue to rely on a contract manufacturing partner in Southeast Asia, for the production of a portion of our Tablo cartridges. If this contract manufacturing partners' facilities were disrupted, by labor disputes, work stoppages, public health crises such as the COVID-19 pandemic, riots, terrorism, vandalism, cyber security attacks, natural disaster, regulatory action or otherwise, it could cause substantial delays in our operations and result in our having insufficient Tablo cartridge in inventory to fulfill orders. For example, in late 2021, supply chain disruptions exacerbated by COVID-19 outbreaks and protocols escalated, and we faced increased supply constraints, which increased freight costs associated with the transportation of Tablo cartridges. Further, to the extent we seek to renew or renegotiate our arrangements with our contract manufacturing partner, and cannot agree to the terms and conditions of future contract manufacturing arrangements, our ability to produce and sell Tablo cartridges could be delayed until we are able to ramp our own in-house manufacturing capabilities to meet demand, or until an alternative manufacturing partner or arrangement is identified, a new contract manufacturing agreement is negotiated and new production lines are established.

We may face additional costs, loss of revenue, significant liabilities, harm to our brand, decreased use of our platform and business disruption if there are any security or data privacy breaches or other unauthorized or improper access.

In connection with various facets of our business, we collect and use a variety of personal information as part of the Tablo data ecosystem, such as name, street address, email addresses, mobile telephone number, and prescription information. Security breaches, computer malware and computer hacking attacks have become more prevalent across industries and may occur on our systems or those of our third-party service providers, suppliers or other partners. Despite the implementation of security measures, our internal computer systems and those of our third-party service providers, suppliers and other partners are vulnerable to damage from computer viruses, hacking and other means of unauthorized access, denial of service and other attacks, natural disasters, terrorism, war and telecommunication and electrical failures. Attacks upon information technology systems are increasing in their frequency, levels of persistence, sophistication and intensity, and are being conducted by sophisticated and organized groups and individuals with a wide range of motives and expertise. Further, we may face increased cybersecurity risks due to our reliance on internet technology and the number of our employees who may work remotely, which may create additional opportunities for cybercriminals to exploit vulnerabilities. In addition to unauthorized access to or acquisition of personal information, confidential information, intellectual property or other sensitive information, such attacks could include the deployment of harmful malware and ransomware, and may use a variety of methods, including denial-of-service attacks, social engineering and other means, to attain such unauthorized access or acquisition or otherwise affect service reliability and threaten the confidentiality, integrity and availability of information. Any failure to prevent or mitigate security breaches or improper access to, or use or disclosure of, our data or consumers' personal information, including information hosted by third party service providers such as Amazon Web Services (AWS), could result in significant liability under applicable data protection laws, such as state breach notification laws and the HIPAA and its implementing regulations. Such an incident may also cause a material loss of revenue from the potential adverse impact to our reputation and brand, affect our ability to retain or attract new users of Tablo and potentially disrupt our business, as well as require significant expenditure of resources to contain, mitigate and remediate the incident. Because the techniques used to obtain unauthorized access, disable or degrade service or sabotage systems change frequently or may be designed to remain dormant until a predetermined or other future event and often are not recognized until launched against a target, we and our partners may be unable to anticipate these techniques or to implement adequate preventative measures. Further, we do not have any direct control over the operations of the facilities or technology of AWS or our other cloud and service providers. Our systems, servers and platforms, those of our cloud service providers, and Tablo's two-way wireless communication system, may be vulnerable to computer viruses or physical or electronic break-ins that our or their security measures may not detect or effectively block, and may be breached due to the actions of outside parties, employee error or misconduct, malfeasance, or a combination of these and, as a result, an unauthorized party may obtain access to our data or the personal information maintained by us or on our behalf. Additionally, outside parties may attempt to fraudulently induce employees to disclose sensitive information in order to gain access to the data and personal information we maintain, including through phishing or other social engineering attacks. Threat actors, including individuals, criminal groups, state sponsored actors or others may be able to circumvent such security measures and misappropriate our confidential or proprietary information, disrupt our

operations, corrupt our data, damage our computers or otherwise impair our reputation and business. Although we currently invest in our resources and infrastructure, we may need to expend significant resources and make significant capital investment in the future to protect against security breaches or to mitigate the impact of any such breaches. In addition, to the extent that our cloud and other service providers experience security breaches that result in the unauthorized or improper use of confidential information, employee information or personal information, we may not be indemnified for any losses resulting from such breaches. Moreover, we are engaging a leading third-party information security consulting firm for virtual CISO advisory services to support our information security program, which will continue to be overseen by our VP of Information Technology. While this consulting firm has significant experience in supporting and managing information security programs, is already involved in various aspects of our cybersecurity risk management program and ongoing cybersecurity operations, and the engagement is designed to enhance our program, there can be no assurance that the integration of external resources for virtual CISO advisory services will be seamless or free of operational or security risks, which could result in unforeseen vulnerabilities or costs. If we are unable to prevent or mitigate the impact of security breaches or other cyber events that impact our operations, our ability to attract and retain new customers, patients, and other partners could be harmed, as they may be reluctant to entrust us with their data, and we could be exposed to litigation and governmental investigations, which could lead to a potential disruption to our business or other adverse consequences.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Form of Amended and Restated Certificate of Incorporation of Outset Medical, Inc.	S-1/A	333-248225	3.1	September 9, 2020
3.2	Form of Amended and Restated Bylaws of Outset Medical, Inc.	S-1/A	333-248225	3.2	September 9, 2020
3.3	Amendment No. 1 To Amended and Restated Bylaws of Outset Medical, Inc., dated January 23, 2025	8-K	001-39513	3.1	January 24, 2025
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A Non-Voting Convertible Preferred Stock	8-K	001-39513	3.1	January 8, 2025
4.1	Form of Common Stock Certificate	S-1/A	333-248225	4.1	September 9, 2020
4.2	Amended and Restated Registration Rights Agreement	S-1	333-248225	4.2	August 21, 2020
4.3	Description of Outset Medical, Inc.'s Securities Registered Pursuant to Section 12 of the Exchange Act	10-K	001-39513	4.5	March 22, 2021
4.4	Warrant Certificate, dated January 8, 2025, issued by Outset Medical, Inc. to Perceptive Credit Holdings IV, LP	8-K	001-39513	4.1	January 8, 2025
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				

* Filed herewith.

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Outset Medical, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2025, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to her/his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations the Company.

November 10, 2025

By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(Principal Executive Officer)

November 10, 2025

By: /s/ Renee Gaeta
Renee Gaeta
Chief Financial Officer
(Principal Financial Officer)

The foregoing certification is being furnished to the Securities and Exchange Commission as an exhibit to the Report and shall not be deemed filed by the Company for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and it is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.
