

**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, 2024**

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 checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input 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 1, 2024, the registrant had 52,542,024 shares of common stock, \$0.001 par value per share, outstanding.

Table of Contents

	<u>Page</u>	
PART I.	<u>FINANCIAL INFORMATION</u>	1
Item 1.	<u>Financial Statements (Unaudited)</u>	1
	<u>Condensed Balance Sheets</u>	1
	<u>Condensed Statements of Operations</u>	2
	<u>Condensed Statements of Comprehensive Loss</u>	3
	<u>Condensed Statements of Stockholders' Equity</u>	4
	<u>Condensed Statements of Cash Flows</u>	6
	<u>Notes to Unaudited Condensed Financial Statements</u>	7
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	16
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u>	22
Item 4.	<u>Controls and Procedures</u>	22
PART II.	<u>OTHER INFORMATION</u>	24
Item 1.	<u>Legal Proceedings</u>	24
Item 1A.	<u>Risk Factors</u>	24
Item 2.	<u>Unregistered Sales of Equity Securities and Use of Proceeds</u>	25
Item 3.	<u>Defaults Upon Senior Securities</u>	25
Item 4.	<u>Mine Safety Disclosures</u>	26
Item 5.	<u>Other Information</u>	26
Item 6.	<u>Exhibits</u>	27
	<u>Signatures</u>	28

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements (unaudited).

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

	<u>September 30,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 33,287	\$ 68,509
Short-term investments	142,346	134,815
Accounts receivable, net	34,259	32,980
Inventories	61,436	49,215
Prepaid expenses and other current assets	3,945	5,700
Total current assets	<u>275,273</u>	<u>291,219</u>
Restricted cash	3,329	3,329
Property and equipment, net	9,492	13,273
Operating lease right-of-use assets	4,312	5,375
Other assets	484	605
Total assets	<u>\$ 292,890</u>	<u>\$ 313,801</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 4,295	\$ 5,827
Accrued compensation and related benefits	14,719	19,005
Accrued expenses and other current liabilities	6,749	13,459
Accrued warranty liability	2,156	3,712
Deferred revenue, current	12,766	11,727
Operating lease liabilities, current	1,745	1,593
Total current liabilities	<u>42,430</u>	<u>55,323</u>
Accrued interest	2,222	896
Deferred revenue	77	101
Operating lease liabilities	3,157	4,482
Term loans	197,182	130,113
Total liabilities	<u>245,068</u>	<u>190,915</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of September 30, 2024 and December 31, 2023; 52,538 and 50,317 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	52	50
Additional paid-in capital	1,111,503	1,084,515
Accumulated other comprehensive income	352	68
Accumulated deficit	(1,064,085)	(961,747)
Total stockholders' equity	<u>47,822</u>	<u>122,886</u>
Total liabilities and stockholders' equity	<u>\$ 292,890</u>	<u>\$ 313,801</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		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	\$ 20,305	\$ 23,531	\$ 59,971	\$ 80,640
Service and other revenue	8,361	6,831	24,251	19,229
Total revenue	<u>28,666</u>	<u>30,362</u>	<u>84,222</u>	<u>99,869</u>
Cost of revenue:				
Cost of product revenue	11,532	16,837	34,680	59,866
Cost of service and other revenue	7,314	6,368	21,725	18,715
Total cost of revenue	<u>18,846</u>	<u>23,205</u>	<u>56,405</u>	<u>78,581</u>
Gross profit	9,820	7,157	27,817	21,288
Operating expenses:				
Research and development	8,139	16,076	30,508	44,775
Sales and marketing	15,417	24,720	54,593	74,038
General and administrative	10,103	11,815	34,231	34,892
Total operating expenses	<u>33,659</u>	<u>52,611</u>	<u>119,332</u>	<u>153,705</u>
Loss from operations	(23,839)	(45,454)	(91,515)	(132,417)
Interest income and other income, net	2,149	2,573	7,718	7,889
Interest expense	(6,068)	(3,213)	(18,046)	(9,258)
Loss before provision for income taxes	<u>(27,758)</u>	<u>(46,094)</u>	<u>(101,843)</u>	<u>(133,786)</u>
Provision for income taxes	182	86	495	411
Net loss	<u>\$ (27,940)</u>	<u>\$ (46,180)</u>	<u>\$ (102,338)</u>	<u>\$ (134,197)</u>
Net loss per share, basic and diluted	<u>\$ (0.55)</u>	<u>\$ (0.93)</u>	<u>\$ (1.98)</u>	<u>\$ (2.72)</u>
Shares used in computing net loss per share, basic and diluted	<u>50,501</u>	<u>49,913</u>	<u>51,685</u>	<u>49,364</u>

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		Nine Months Ended	
	September 30,		September 30,	
	2024	2023	2024	2023
Net loss	\$ (27,940)	\$ (46,180)	\$ (102,338)	\$ (134,197)
Other comprehensive (loss) income:				
Unrealized gain on available-for-sale securities	654	140	284	311
Comprehensive loss	\$ (27,286)	\$ (46,040)	\$ (102,054)	\$ (133,886)

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

Outset Medical, Inc.
Condensed Statement of Stockholders' Equity
(Unaudited)
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehen- sive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2023	50,317	\$ 50	\$ 1,084,515	\$ 68	\$ (961,747)	\$ 122,886
Issuance of common stock through employee stock purchase plan	776	1	2,079	—	—	2,080
Issuance of common stock for settlement of RSUs	607	1	294	—	—	295
Stock option exercises	2	—	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	51,702	\$ 52	\$ 1,095,097	\$ (258)	\$ (1,001,691)	\$ 93,200
Issuance of common stock for settlement of RSUs	312	—	—	—	—	—
Stock option exercises	70	—	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	52,084	\$ 52	\$ 1,104,994	\$ (302)	\$ (1,036,145)	\$ 68,599
Issuance of common stock through employee stock purchase plan	264	—	121	—	—	121
Issuance of common stock for settlement of RSUs	190	—	—	—	—	—
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	52,538	\$ 52	\$ 1,111,503	\$ 352	\$ (1,064,085)	\$ 47,822

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

Outset Medical, Inc.
Condensed Statement of Stockholders' Equity
(Unaudited)
(in thousands)

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehen- sive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance as of December 31, 2022	48,465	\$ 48	\$ 1,035,456	\$ (564)	\$ (788,950)	\$ 245,990
Issuance of common stock through employee stock purchase plan	307	1	4,593	—	—	4,594
Issuance of common stock for settlement of RSUs	282	—	—	—	—	—
Stock option exercises	162	—	684	—	—	684
Stock-based compensation expense	—	—	8,538	—	—	8,538
Unrealized gain on available-for-sale securities	—	—	—	451	—	451
Net loss	—	—	—	—	(43,971)	(43,971)
Balance as of March 31, 2023	49,216	\$ 49	\$ 1,049,271	\$ (113)	\$ (832,921)	\$ 216,286
Issuance of common stock for settlement of RSUs	165	—	—	—	—	—
Stock option exercises	248	1	1,042	—	—	1,043
Stock-based compensation expense	—	—	10,105	—	—	10,105
Unrealized loss on available-for-sale securities	—	—	—	(280)	—	(280)
Net loss	—	—	—	—	(44,046)	(44,046)
Balance as of June 30, 2023	49,629	\$ 50	\$ 1,060,418	\$ (393)	\$ (876,967)	\$ 183,108
Issuance of common stock through employee stock purchase plan	252	—	2,916	—	—	2,916
Issuance of common stock for settlement of RSUs	117	—	—	—	—	—
Stock option exercises	175	—	1,186	—	—	1,186
Stock-based compensation expense	—	—	10,893	—	—	10,893
Unrealized gain on available-for-sale securities	—	—	—	140	—	140
Net loss	—	—	—	—	(46,180)	(46,180)
Balance as of September 30, 2023	50,173	\$ 50	\$ 1,075,413	\$ (253)	\$ (923,147)	\$ 152,063

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,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (102,338)	\$ (134,197)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	24,411	29,536
Depreciation and amortization	4,322	4,364
Non-cash lease expense	1,063	919
Non-cash interest expense	1,898	1,377
Amortization of premium on investments, net	(3,890)	(5,099)
Provision for inventories	644	672
Loss on disposal of property and equipment	34	106
Allowance for credit losses	1,813	141
Changes in operating assets and liabilities:		
Accounts receivable	(3,092)	(7,564)
Inventories	(12,989)	2,607
Prepaid expenses and other assets	1,848	440
Accounts payable	(1,507)	2,251
Accrued compensation and related benefits	(3,991)	25
Accrued expenses and other current liabilities	(6,327)	(4,108)
Accrued warranty liability	(1,556)	447
Deferred revenue	1,015	2,114
Operating lease liabilities	(1,173)	(962)
Net cash used in operating activities	<u>(99,815)</u>	<u>(106,931)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(869)	(2,387)
Purchases of investment securities	(150,467)	(121,262)
Maturities of investment securities	147,121	183,250
Net cash (used in) provided by investing activities	<u>(4,215)</u>	<u>59,601</u>
Cash flows from financing activities:		
Proceeds from stock option exercises and ESPP purchases	2,284	10,423
Proceeds from issuance of term loans, net of issuance costs	66,524	—
Net cash provided by financing activities	<u>68,808</u>	<u>10,423</u>
Net decrease in cash, cash equivalents and restricted cash	(35,222)	(36,907)
Cash, cash equivalents and restricted cash as of beginning of period	71,838	76,533
Cash, cash equivalents and restricted cash as of end of period	<u>\$ 36,616</u>	<u>\$ 39,626</u>
Supplemental cash flow disclosures:		
Cash paid for income taxes	<u>\$ 472</u>	<u>\$ 403</u>
Cash paid for interest	<u>\$ 15,537</u>	<u>\$ 1,836</u>
Cash paid for amounts included in the measurement of operating lease liabilities	<u>\$ 1,173</u>	<u>\$ 962</u>
Supplemental non-cash investing and financing activities:		
Capital expenditures included in accounts payable and accrued expenses	<u>\$ 8</u>	<u>\$ 207</u>
Transfer of inventories to property and equipment	<u>\$ 148</u>	<u>\$ —</u>
Right-of-use assets obtained in exchange for operating lease liabilities	<u>\$ —</u>	<u>\$ 528</u>

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.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. During the nine months ended September 30, 2024 and 2023, the Company incurred a net loss of \$102.3 million and \$134.2 million, respectively, and cash outflow from operating activities of \$99.8 million and \$106.9 million, respectively. As of September 30, 2024, the Company had an accumulated deficit of \$1.1 billion.

As of September 30, 2024, the Company had cash, cash equivalents, restricted cash and short-term investments of \$179.0 million. The Company is required to comply with certain covenants under the SLR Credit Facility Agreements (as defined in Note 7) including ones relating to financial reporting and the delivery of an unqualified audit opinion, the maintenance of minimum cash or revenue, the incurrence of additional debt, and its ability to make capital expenditures or declare dividends. If the Company fails to comply with any covenants, payments or other terms of either SLR Credit Facility Agreement, its agent or lender, as applicable, could declare an event of default, which would give it 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 SLR Credit Facility Agreements 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 significant expenses for the foreseeable future and to incur operating losses in the near term while the Company makes investments to support its anticipated growth.

Furthermore, on September 23, 2024, the Company received notice from the Listing Qualifications staff of the Nasdaq Stock Market LLC (Nasdaq) that it no longer complied with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market. If the Company is unable to regain compliance with the minimum bid price requirement within the applicable compliance period, or is unable to otherwise maintain compliance with other applicable Nasdaq listing rules, it may not be able to maintain the listing of its common stock on Nasdaq, which could adversely affect its ability to issue additional securities or obtain additional financing on terms acceptable to it, or at all.

Management believes that the Company's existing cash, cash equivalents, short-term investments, cash generated from sales, and proceeds received from the debt financing described in Note 7, 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, 2024 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, 2023 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, 2023, which are included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2023 filed with the Securities and Exchange Commission (SEC) on February 21, 2024 (2023 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

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* (ASU 2023-07), which requires that an entity disclose significant segment expenses impacting profit and loss that are regularly provided to the chief operating decision maker. The update is required to be applied retrospectively to prior periods presented, based on the significant segment expense categories identified and disclosed in the period of adoption. This ASU guidance is effective for our Annual Report on Form 10-K for the year ended December 31, 2024, and subsequent interim periods, with early adoption permitted. The Company is currently evaluating the impact of the adoption of ASU 2023-07 on its financial statements and disclosures.

In December 2023, the FASB issued ASU No. 2023-09, *Improvements to Income Tax Disclosures* (ASU 2023-09), which requires that an entity disclose specific categories in the effective tax rate reconciliation as well as provide additional information for reconciling items that meet a quantitative threshold. Further, this ASU requires certain disclosures of state versus federal income tax expense and taxes paid. This ASU is effective for our Annual Report on Form 10-K for the year ended December 31, 2025, with early adoption permitted. The Company does not expect the adoption of ASU 2023-09 to have a material impact on its financial statements.

In March 2024, the SEC adopted rules intended to enhance and standardize climate-related disclosures in registration statements and annual reports. The new rules will require disclosure of material climate-related risks, including the material impacts of these risks to the Company, the quantification of material impacts to the Company as a result of severe weather events and other natural conditions and Board of Directors' oversight and risk management activities. The new rules follow a compliance phase-in timeline based on a company's filing status. Large accelerated filers and accelerated filers (other than smaller reporting companies) are required to first incorporate such disclosures for fiscal years 2025 and 2026, respectively, followed by greenhouse gas-related disclosures, if material, for fiscal years 2026 and 2027, respectively. Smaller reporting companies are required to first incorporate such disclosures for fiscal year 2027 and are not required to report greenhouse gas emissions data. In April 2024, the SEC determined to voluntarily stay the final rules pending certain legal challenges. The Company is currently evaluating the impact of these new rules on its financial statements and disclosures.

Significant Accounting Policies

There have been no new or material changes to the Company's significant accounting policies as described in its 2023 Annual Report that have had a material impact on the Company's condensed financial statements and related notes.

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,	
	2024	2023	2024	2023
Consoles	\$ 7,709	\$ 12,506	\$ 24,080	\$ 51,053
Consumables	12,596	11,025	35,891	29,587
Total product revenue	20,305	23,531	59,971	80,640
Service and other revenue	8,361	6,831	24,251	19,229
Total revenue	\$ 28,666	\$ 30,362	\$ 84,222	\$ 99,869

Remaining Performance Obligations and Contract Liabilities

As of September 30, 2024, 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 \$12.9 million, which is recorded as deferred revenue on the Company's condensed balance sheets. Of that amount, \$12.8 million will be recognized as revenue during the next 12 months and \$0.1 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, 2024, the Company recognized \$2.0 million and \$10.9 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, 2024			
		Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	\$ 16,136	\$ —	\$ —	\$ 16,136
Short-term investments:					
U.S. Treasury securities	Level 1	72,762	158	—	72,920
U.S. government-sponsored enterprises debt securities	Level 2	11,520	14	—	11,534
Corporate debt	Level 2	57,712	181	(1)	57,892
Commercial paper	Level 2	—	—	—	—
Total cash equivalents and short-term investments		<u>\$ 158,130</u>	<u>\$ 353</u>	<u>\$ (1)</u>	<u>\$ 158,482</u>

	Valuation Hierarchy	December 31, 2023			
		Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	\$ 44,883	\$ —	\$ —	\$ 44,883
Short-term investments:					
U.S. Treasury securities	Level 1	53,790	58	(32)	53,816
U.S. government-sponsored enterprises debt securities	Level 2	29,645	24	(38)	29,631
Corporate debt	Level 2	33,214	56	—	33,270
Commercial paper	Level 2	18,097	5	(4)	18,098
Total cash equivalents and short-term investments		<u>\$ 179,629</u>	<u>\$ 143</u>	<u>\$ (74)</u>	<u>\$ 179,698</u>

As of September 30, 2024, the remaining contractual maturities for available-for-sale securities were one month to thirteen months.

The following tables present the breakdown of the available-for-sale debt securities with unrealized losses as of September 30, 2024, and December 31, 2023 (in thousands):

	September 30, 2024					
	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
Corporate debt	\$ 2,659	\$ (1)	\$ —	\$ —	\$ 2,659	\$ (1)
Total	<u>\$ 2,659</u>	<u>\$ (1)</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 2,659</u>	<u>\$ (1)</u>

	December 31, 2023					
	Unrealized losses less than 12 months		Unrealized losses 12 months or greater		Total	
	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses	Fair Value	Unrealized Losses
U.S. Treasury securities	\$ 8,416	\$ (16)	\$ 17,925	\$ (16)	\$ 26,341	\$ (32)
U.S. government-sponsored enterprises debt securities	18,757	(22)	8,488	(16)	27,245	(38)
Corporate debt	11,291	(4)	—	—	11,291	(4)
Total	<u>\$ 38,464</u>	<u>\$ (42)</u>	<u>\$ 26,413</u>	<u>\$ (32)</u>	<u>\$ 64,877</u>	<u>\$ (74)</u>

The unrealized losses on the Company's available-for-sale debt securities were caused by interest rate increases. The contractual terms of those investments do not permit the issuer to settle the securities at a price less than the amortized cost basis of the investments. As of September 30, 2024, the Company does not intend to sell the investments, and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity. Additional factors considered in determining the treatment of unrealized losses include the financial condition and near-term prospects of the investee, the extent of the loss related to the credit of the issuer, and the expected cash flows from the security. For the three and nine months ended September 30, 2024 and 2023, the Company did not recognize credit loss related to available-for-sales debt securities.

5. Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

As of September 30, 2024 and December 31, 2023, the restricted cash balance of \$3.3 million, was related to collateral for the Company's building leases in San Jose, CA and Tijuana, Mexico.

The following table provides a reconciliation of cash, cash equivalents and restricted cash that sum to the total of the amounts shown in the accompanying condensed statements of cash flows (in thousands):

	September 30,	
	2024	2023
Cash and cash equivalents	\$ 33,287	\$ 36,297
Restricted cash	3,329	3,329
Total cash, cash equivalents and restricted cash	<u>\$ 36,616</u>	<u>\$ 39,626</u>

Accounts Receivable

Accounts receivable are recorded at invoice value, net of any allowance for credit losses. The allowance for credit losses is based on the Company's assessment of its best estimate of the amount of credit losses in customer accounts. The Company regularly reviews the allowance by considering factors such as existing contractual payment terms, historical collection experience, the financial position of the customer and information provided by credit rating services, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay.

The Company writes off accounts receivable when the Company has exhausted collection efforts without success, and payments subsequently received on such receivables are credited to the allowance in the period the payment is received. Credit losses from continuing operations have consistently been within management's expectations.

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

Balance as of December 31, 2023	\$ 203
Increase in allowance	1,821
Write-offs	(7)
Balance as of September 30, 2024	<u>\$ 2,017</u>

Inventories

Inventories consist of the following (in thousands):

	September 30, 2024	December 31, 2023
Raw materials	\$ 25,138	\$ 18,706
Work in process	13,911	8,728
Finished goods	22,387	21,781
Total inventories	<u>\$ 61,436</u>	<u>\$ 49,215</u>

Accrued Expenses and Other Current Liabilities

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

	September 30, 2024	December 31, 2023
Inventory	\$ 1,384	\$ 3,395
Research and development expenses	116	1,050
Professional services	716	1,153
Customer rebates	1,738	2,100
Other	2,795	5,761
Total accrued expenses and other current liabilities	<u>\$ 6,749</u>	<u>\$ 13,459</u>

6. Commitments and Contingencies

Litigation

On August 29, 2024, a purported stockholder class action lawsuit (the Porcelli Complaint), *Porcelli, et al. 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, naming the Company, its Chief Executive Officer, and Chief Financial Officer as defendants. On October 18, 2024, a second purported stockholder class action lawsuit (the Plymouth Complaint), *Plymouth County Retirement Association v. Outset Medical, Inc, et al.*, 5:24-cv-06124-HSG, was filed in the U.S. District Court for the Northern District of California. The second lawsuit additionally names the Company's former Chief Financial Officer as a defendant. The Porcelli Complaint alleges that between August 1, 2022 and August 7, 2024, the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (Exchange Act) by making false or misleading statements about 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 alleges the same violations between September 15, 2020 and August 7, 2024. The Company intends to vigorously defend against this litigation. The cases are at a very early stage and there can be no assurance that the Company will be successful in its defense. For this same reason, 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, 2024	December 31, 2023
Principal of term loans	\$ 200,000	\$ 133,476

Unamortized debt discount	(2,818)	(3,363)
Term loans, noncurrent	\$ 197,182	\$ 130,113

SLR Credit Facilities

On November 3, 2022 (the Closing Date), 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 (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).

The maximum amount the Company is permitted to borrow under the SLR Credit Facilities is subject to certain overall borrowing limitations that are tied to achieving certain specified revenue milestones and limit the maximum principal amount outstanding under the SLR Credit Facilities. As of September 30, 2024, the Company borrowed an aggregate principal amount of \$200.0 million under the SLR Term Loan Facility, the full amount available under the borrowing limitations.

SLR Term Loan Facility

Under the SLR Loan Agreement, as subsequently amended on December 11, 2023, the Term Loan Lenders agreed to extend term loans to the Company in an aggregate principal amount of up to \$250.0 million, comprised of (i) a term loan of \$100.0 million (the Term A Loan), (ii) term loans in an aggregate principal amount of up to \$100.0 million that was provided for in two increments, one of \$33.5 million (the Term B-1 Loan) and one of \$66.5 million (the Term B-2 Loan) and (iii) one or more term loans in an aggregate principal amount of up to \$50.0 million (Term C Loans). Each Term A Loan, Term B Loan and Term C Loan is referred to single as a Term Loan and are referred to collectively as the Term Loans. The Term C Loans are subject to compliance with the borrowing limitations, Term Loan Lenders' credit approval and the achievement of a specified net revenue milestone on or before June 30, 2025 and if available, would remain available for funding until one business day prior to November 1, 2027.

Any principal amount outstanding under the Term Loans will accrue interest at a rate per annum equal to one-month term Secured Overnight Financing Rate (term SOFR) (subject to a 2.75% floor), plus 5.15% (10.32% as of September 30, 2024), payable monthly in arrears. The Company is permitted to make interest-only payments on the Term Loans through November 30, 2026. Any principal amounts outstanding under the Term Loans, if not repaid sooner, are due and payable on November 1, 2027 (the Maturity Date). The Company is obligated to pay Agent (i) a non-refundable facility fee in the amount of \$750,000 in respect of the Term A Loan, (ii) a non-refundable facility fees in the aggregate amount of \$750,000 in respect of the Term B-1 and B-2 Loans and (iii) a non-refundable facility fee in the amount of \$375,000 in respect of the Term C Loan, to be due and payable upon the earliest to occur of (a) the funding of the first Term C Loan, (b) one day prior to the Maturity Date and (c) the prepayment of the Term Loans. In addition, the Company is obligated to pay a final fee equal to 4.75% of the aggregate amount of the Term Loans funded, such final fee to be due and payable upon the earliest to occur of (i) the Maturity Date, (ii) the acceleration of the Term Loans and (iii) the prepayment of the Term Loans. The Company may voluntarily prepay the outstanding Term Loans, subject to a prepayment premium of (i) 3.0% of the principal amount of the Term Loan, if prepaid prior to or on the first anniversary of the Closing Date, (ii) 2.0% of the principal amount of the Term Loan, if prepaid after the first anniversary of the Closing Date through and including the second anniversary of the Closing Date, or (iii) 1.0% of the principal amount of the Term Loan if prepaid after the second anniversary of the Closing Date and prior to the Maturity Date.

SLR Revolver

The SLR Revolving Credit Agreement provides for an asset-based revolving credit facility with aggregate revolving commitments of \$25.0 million (the Initial Revolver Commitment). The Company may request to increase the aggregate revolving commitments by \$25.0 million (the Additional Tranche) to an aggregate amount of \$50.0 million, subject to ABL Lender's approval. Amounts available to be drawn under the SLR Revolver are equal to the lesser of (i) outstanding revolving commitments under the SLR Revolving Credit Agreement and (ii) a borrowing base (the Borrowing Base) equal to the sum of (a) 85% of eligible accounts receivable, plus (b) 25% of eligible inventory (not to exceed the lesser of 50% of the Borrowing Base and \$5.0 million), minus (c) customary reserves, minus (d) unposted cash. As of September 30, 2024, no amounts were outstanding under the SLR Revolver. As a result of the overall borrowing limitations set forth in the SLR Credit Facilities, amounts under the SLR Revolver are not currently available. As of September 30, 2024, the Company has not requested or received ABL Lender's approval of the Additional Tranche.

Any principal amount outstanding under the SLR Revolver will accrue interest at a rate per annum equal to one-month term SOFR (subject to a 2.75% floor), plus 3.20%, payable monthly in arrears. Interest on any borrowing is payable monthly. The Company is obligated to pay Lender (i) a non-refundable facility fee in the amount of \$187,500 in respect of the Initial Revolver Commitment, (ii) a non-refundable facility fee in the amount of \$187,500 in respect of the Additional Tranche, to be due and payable upon activation of the Additional Tranche, (iii) a commitment fee of 0.50% per annum of the average daily unused portion of the then commitment amount, payable monthly and (iv) a collateral monitoring fee of 0.10% per month of the average daily Borrowing Base

during the prior month, payable monthly. The Company may terminate the SLR Revolver at any time, subject to a termination fee of (i) 2.0% of the aggregate revolving commitments then in effect, if terminated prior to or on the first anniversary of the Closing Date, (ii) 1.0% of the aggregate revolving commitments then in effect, if terminated after the first anniversary of the Closing Date through and including the second anniversary of the Closing Date, or (iii) 0.5% of the aggregate revolving commitments then in effect, if terminated after the second anniversary of the Closing Date through and including the third anniversary of the Closing Date. Such termination fee is waived if the SLR Revolver is terminated after the third anniversary of the Closing Date and prior to the Maturity Date.

Subject to customary exceptions and restrictions, the Company may borrow, repay and reborrow varying amounts under the SLR Revolver at any time subject to the overall borrowing limitations. If at any time the outstanding amount under the SLR Revolver exceeds the lesser of (i) the aggregate revolving commitments then in effect and (ii) the Borrowing Base then in effect, the Company will be required to prepay outstanding amounts under the SLR Revolver.

The SLR Revolver shall expire on November 1, 2027.

Other Terms of the SLR Credit Facilities

As security for its obligations under the SLR Credit Facilities, the Company granted Agent, for the benefit of the Term Loan Lenders, and ABL Lender a security interest in substantially all of the assets of the Company, including the Company's intellectual property, subject to certain exceptions.

The SLR Credit Facility Agreements contain 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. The agreements also include a financial covenant that, beginning with the fiscal quarter ended December 31, 2023, the Company must either (i) maintain certain levels of cash and cash equivalents in accounts subject to control agreements in favor of Agent and ABL Lender of at least 50% of the sum of (a) the outstanding obligations under the Term Loans (as defined below) and (b) the amount of the Company's accounts payable that have not been paid within 120 days from the invoice date thereof or (ii) generate net product and product related revenue in excess of specified amounts and maintain gross profit margins in excess of specified percentages, in each case, for applicable measuring periods.

In addition, the SLR Credit Facility Agreements contain customary events of default that entitle Agent, under the SLR Loan Agreement, and ABL Lender, under the SLR Revolving Credit Agreement, to cause the Company's indebtedness under the SLR Loan Agreement or SLR Revolving Credit Agreement, as applicable, to become immediately due and payable, and to exercise remedies against the Company and the collateral securing the obligations owed under the applicable SLR Credit Facility Agreement. Under the SLR Credit Facility Agreements, an event of default will occur if, among other things, the Company fails to make payments under either SLR Credit Facility Agreement, the Company breaches covenants under either SLR Credit Facility Agreement, subject to specified cure periods with respect to certain breaches, the Agent or ABL Lender, as applicable, determine that a material adverse change has occurred under the SLR Loan Agreement or SLR Revolving Credit Agreement, as applicable, 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 SLR Credit Facility Agreements.

The debt issuance costs and the facility fees related to the Term A and B Loans were recorded as a direct deduction from the term loans balance on the balance sheets and are being recognized as non-cash interest expense over the term of the loans using the effective interest method, along with the final payment fee. The facility fees related to the Initial Revolver Commitment were recorded as deferred financing costs and are being recognized as non-cash interest expense over their respective commitment period using straight-line method.

8. Equity Incentive Plan

Equity Incentive Plans

As of September 30, 2024, 3,218,000 shares were reserved for future issuance under the 2020 Equity Incentive Plan (2020 Plan).

Employee Share Purchase Plan (ESPP)

As of September 30, 2024, 667,000 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 our 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 either: (i) 25% on the first anniversary of the original vesting 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 original vesting date, with the balance vesting quarterly over the remaining two years. 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. The PSUs are earned and vest based on achievement against two metrics:

- The “Home PSUs” 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 (performance-based vesting conditions).
- The “Relative TSR PSUs” 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 on, or after certification of achievement following, the third anniversary of the grant date (market-based vesting conditions).

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 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.

The grant date for the Home PSUs is 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 date for the Home PSUs has been established, the related stock-based compensation expense is 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 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,	
	2024	2023	2024	2023
Cost of revenue	\$ 296	\$ 620	\$ 1,092	\$ 1,381
Research and development	1,400	2,793	6,025	8,232
Sales and marketing	945	3,765	4,898	9,908
General and administrative	3,747	3,715	12,396	10,015
Total stock-based compensation expense	<u>\$ 6,388</u>	<u>\$ 10,893</u>	<u>\$ 24,411</u>	<u>\$ 29,536</u>

9. Income Taxes

For each of the three and nine months ended September 30, 2024 and 2023, the Company incurred an income tax provision of an insignificant amount, which primarily related to foreign income taxes related to 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.

10. 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,	
	2024	2023
Stock options to purchase common stock	1,521	1,978
Restricted stock units	3,961	2,760
Performance stock units	273	95
Shares committed under ESPP	319	42
Warrant to purchase common stock	63	63
Total	6,137	4,938

11. 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 is taking 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 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.

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, 2024	
Cost of revenue	\$	530
Research and development		1,260
Sales and marketing		1,884
General and administrative		475
Total	\$	4,149

The changes in liabilities resulting from the restructuring accruals, which were recorded in accrued expenses and other current liabilities on the accompanying condensed balance sheets, were as follows (in thousands):

Balance as of December 31, 2023	\$	854
Charges		4,149
Payments and other adjustments		(4,920)
Balance as of September 30, 2024	\$	83

12. Subsequent Event

On October 18, 2024, a second purported stockholder class action lawsuit was filed against the Company, certain of its officers and a former officer (see Note 6).

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 2023 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 2023 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 (FSEs). 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 by up to 80% in the intensive care unit. 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. We plan to continue leveraging our commercial infrastructure to broaden our installed base in the acute care market, 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 (IDE) trial, patients reported specific quality of life improvements compared to their experience on the incumbent home dialysis machine. To penetrate this market successfully, we 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 (TCUs) 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 cartridges, and services, which generates significant total revenue over the life of Tablo consoles. Our total revenues were \$28.7 million and \$30.4 million for the three months ended September 30, 2024 and 2023, respectively, and \$84.2 million and \$99.9 million for the nine months ended September 30, 2024 and 2023, 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 50% of our total full-time employees as of September 30, 2024. 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.

Recent Developments

In July 2023, we received a warning letter (the Warning Letter) from the FDA that raised two observations. The first observation asserted that certain content reviewed by the FDA and found on our website promoted continuous renal replacement therapy (CRRT), a modality outside of the current indications for Tablo. The second observation asserted that TabloCart with Prefiltration requires prior 510(k) clearance for marketing authorization. TabloCart with Prefiltration is an accessory to Tablo launched in the third quarter of 2022. We believe the concern raised by the first observation regarding CRRT promotion has been effectively addressed through a thorough review of existing promotional materials and practices. We believe the concern raised by the second observation regarding TabloCart with Prefiltration has also been effectively addressed. Although we evaluated TabloCart with Prefiltration prior to marketing and distributing the product and concluded that no marketing authorization was necessary, we paused distribution of TabloCart with Prefiltration pending the FDA's review and clearance of a 510(k) application that we submitted in September 2023. In early May 2024, we received 510(k) clearance from the FDA for TabloCart with Prefiltration, and we have resumed distribution of TabloCart with Prefiltration. We believe we have now taken appropriate measures to fully address the matters raised in the Warning Letter.

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, sub-acute long-term acute care hospitals (LTACHs) and skilled nursing facilities (SNFs). 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 as we resume distribution of TabloCart with Prefiltration, as well as the success of our initiatives to optimize our commercial organization, infrastructure and sales processes to support the growth of our business in the acute care market 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 Expansion

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 of 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 performance, to better support our field service team 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.

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 two organizational restructurings implemented in the fourth quarter of 2023 and second quarter of 2024. In connection with steps we are taking to help optimize our commercial organization, in the third quarter of 2024, we completed an additional restructuring primarily impacting our commercial organization. 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, 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 we expect these negative impacts to continue through at least the remainder of 2024. Beginning in 2022, our existing and prospective customers faced shortages of skilled nurses and other clinical personnel as well as increased labor costs, combined with economic pressures resulting from general economic and financial market conditions, primarily escalating inflation, tightening hospital operating budgets and increased scrutiny of capital purchase decisions, all of which generally have the effect of lengthening the average sales cycle and elongating the timing of installations. These factors negatively impacted our customer base on pipeline development and installation schedules, which, in turn, negatively impacted our bookings, delayed our shipments and adversely impacted our revenues for 2022 and, to a lesser extent, 2023. We have generally seen some stabilization in these challenging labor market dynamics for healthcare providers during 2023 and thereafter as compared to 2022. Moreover, we believe Tablo offers automation and ease-of-use benefits over traditional machines that can enhance our existing and potential customers' ability to support their patient populations despite staffing shortages. However, 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, cybersecurity events or otherwise, 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.

In 2022, we launched a pilot clinical and administrative services program designed to help bridge our healthcare provider customers, particularly those challenged by staffing shortages, as they transition from using an outsourced inpatient dialysis provider to offering on-site inpatient dialysis services on their own. In return for a fair market value service fee, we assign members of our own employed nurses on a temporary basis to support participating providers to launch and manage an inpatient dialysis program using

Tablo and, as full-time staff is hired, to help train and onboard those nurses. However, our pilot clinical and administrative services program may not be successful in achieving the objectives we intend and anticipate, may fail to meet our customers' expectations, may not generate sufficient returns to justify our investment, or may result in unanticipated costs, which could harm our reputation and customer relationships, and adversely impact our operating margins and results of operations.

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 (to our Mexico-based contract manufacturer and, more recently, 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.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2024 and 2023 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue:				
Product revenue	\$ 20,305	\$ 23,531	\$ 59,971	\$ 80,640
Service and other revenue	8,361	6,831	24,251	19,229
Total revenue	28,666	30,362	84,222	99,869
Cost of revenue:				
Cost of product revenue	11,532	16,837	34,680	59,866
Cost of service and other revenue	7,314	6,368	21,725	18,715
Total cost of revenue	18,846	23,205	56,405	78,581
Gross profit	9,820	7,157	27,817	21,288
Operating expenses:				
Research and development	8,139	16,076	30,508	44,775
Sales and marketing	15,417	24,720	54,593	74,038
General and administrative	10,103	11,815	34,231	34,892
Total operating expenses	33,659	52,611	119,332	153,705
Loss from operations	(23,839)	(45,454)	(91,515)	(132,417)
Interest income and other income, net	2,149	2,573	7,718	7,889
Interest expense	(6,068)	(3,213)	(18,046)	(9,258)
Loss before provision for income taxes	(27,758)	(46,094)	(101,843)	(133,786)
Provision for income taxes	182	86	495	411
Net loss	\$ (27,940)	\$ (46,180)	\$ (102,338)	\$ (134,197)

Comparison of the Three and Nine Months Ended September 30, 2024 and 2023

Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
<i>(dollars in thousands)</i>								
Revenue:								
Product revenue	\$ 20,305	\$ 23,531	\$ (3,226)	(14)%	\$ 59,971	\$ 80,640	\$ (20,669)	(26)%
Service and other revenue	8,361	6,831	1,530	22%	24,251	19,229	5,022	26%
Total revenue	\$ 28,666	\$ 30,362	(1,696)	(6)%	\$ 84,222	\$ 99,869	(15,647)	(16)%

Product revenue decreased by \$3.2 million or 14% for the three months ended September 30, 2024 as compared to the same period in the prior year. This decrease was driven by a \$4.8 million decrease in console revenue due to fewer consoles being sold in the current year, which was partially offset by a \$1.6 million increase in consumable revenue due to growth in our console installed base.

Product revenue decreased by \$20.7 million, or 26% for the nine months ended September 30, 2024 as compared to the same period in the prior year. This decrease was driven by a \$27.0 million decrease in console revenue due to fewer consoles being sold in the current year, which was offset by a \$6.3 million increase in consumable revenue attributable to growth in our console installed base.

Service and other revenue increased for the three and nine months ended September 30, 2024 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 September 30,		Change		Nine Months Ended September 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Gross profit and gross margin:								
Gross profit	\$ 9,820	\$ 7,157	\$ 2,663	37%	\$ 27,817	\$ 21,288	\$ 6,529	31%
Gross margin	34.3 %	23.6 %			33.0 %	21.3 %		

Gross profit increased for the three and nine months ended September 30, 2024 as compared to the same periods in the prior year. Gross margin improved by 10.7 percentage points for the three months ended September 30, 2024 and 11.7 percentage points for the nine months ended September 30, 2024 as compared to the same periods in the prior year. These improvements in gross profit and gross margin were primarily driven by a higher mix of consumable and service and other revenue than consoles in the current year as compared to the prior year. Consumables had a higher gross margin than consoles and had improved gross margin year over year. The higher consumable gross margin mainly resulted from lower cost per unit as well as a higher average selling price for consumables.

Operating Expenses

<i>(dollars in thousands)</i>	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Operating expenses:								
Research and development	\$ 8,139	\$ 16,076	\$ (7,937)	(49)%	\$ 30,508	\$ 44,775	\$ (14,267)	(32)%
Sales and marketing	15,417	24,720	(9,303)	(38)%	54,593	74,038	(19,445)	(26)%
General and administrative	10,103	11,815	(1,712)	(14)%	34,231	34,892	(661)	(2)%
Total operating expenses	\$ 33,659	\$ 52,611	(18,952)	(36)%	\$ 119,332	\$ 153,705	(34,373)	(22)%

Research and development expenses decreased for the three and nine months ended September 30, 2024 as compared to the same periods 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 resulting from our cost reduction efforts implemented in the fourth quarter of 2023 and in 2024.

Sales and marketing expenses decreased for the three and nine months ended September 30, 2024 as compared to the same periods in the prior year. The decrease was primarily driven by an overall decrease in compensation-related and stock-based compensation expense, travel and consulting expenses resulting from our cost reduction efforts implemented in the fourth quarter of 2023 and in 2024. The decreases for the nine months ended September 30, 2024 were partially offset by higher freight expenses due to higher consumable unit sales.

General and administrative expenses decreased for the three months ended September 30, 2024 as compared to the same period in the prior year. The decrease was primarily due to an overall decrease in compensation-related expense and consulting expense from our cost reduction efforts implemented in the fourth quarter of 2023 and in 2024. Our insurance costs also decreased as compared to the prior year period.

General and administrative expenses decreased for the nine months ended September 30, 2024 as compared to the same period in the prior year. The decrease was primarily due to an overall decrease in consulting, compensation-related and travel expenses resulting from our cost reduction efforts implemented in the fourth quarter of 2023 and in 2024. Our insurance costs also decreased as compared to the prior year periods. These decreases were partially offset by \$1.8 million of allowance for credit losses recorded in the second quarter of 2024 and an increase in stock-based compensation expense.

Other Income (Expenses), Net

<i>(dollars in thousands)</i>	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
	2024	2023	\$	%	2024	2023	\$	%
Other income (expenses), net:								
Interest income and other income, net	\$ 2,149	\$ 2,573	\$ (424)	(16)%	\$ 7,718	\$ 7,889	\$ (171)	(2)%
Interest expense	(6,068)	(3,213)	(2,855)	89%	(18,046)	(9,258)	(8,788)	95%
Total other expenses, net	\$ (3,919)	\$ (640)	(3,279)	512%	\$ (10,328)	\$ (1,369)	(8,959)	654%

The changes in interest income and other income, net for the three and nine months ended September 30, 2024 as compared to the same periods in the prior year were driven by the changes in interest rates.

The increases in interest expense for the three and nine months ended September 30, 2024 were primarily due to a higher outstanding balance under the SLR Term Loan Facility in 2024.

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 redeemable convertible preferred stock and common stock, revenue from sales, debt financing, and proceeds from employee exercise of stock options and ESPP purchases.

As of September 30, 2024, we had cash, cash equivalents, restricted cash, and short-term investments of \$179.0 million. We are required to comply with certain covenants under the SLR Credit Facility Agreements, including ones relating to financial reporting and the delivery of an unqualified audit opinion, the maintenance of minimum cash or revenue, the incurrence of additional debt, and our ability to make capital expenditures or declare dividends. If we fail to comply with any covenants, payments or other terms of either SLR Credit Facility Agreement, our agent or lender, as applicable, could declare an event of default, which would give it the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. For further details, see Note 7 of the accompanying condensed financial statements above, as well as the section entitled "Risk Factors" under Part II, Item 1A below.

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 significant expenses for the foreseeable future and 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. 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.

On September 23, 2024, we received notice from the Listing Qualifications staff of Nasdaq that we no longer complied with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market. If we are unable to regain compliance with the minimum bid price requirement within the applicable compliance period, or are unable to otherwise maintain compliance with other applicable Nasdaq listing rules, we may not be able to maintain the listing of our common stock on Nasdaq, which could adversely affect our ability to issue additional securities or obtain additional financing on terms acceptable to us, or at all. For further details, see the section entitled "Risk Factors" under Part II, Item 1A below.

We believe that our existing cash, cash equivalents and short-term investments, cash generated from sales, and proceeds received from the debt financing described in Note 7 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,	
	2024	2023
Net cash (used in) provided by:		
Operating activities	\$ (99,815)	\$ (106,931)
Investing activities	(4,215)	59,601
Financing activities	68,808	10,423
Net decrease in cash, cash equivalents and restricted cash	<u>\$ (35,222)</u>	<u>\$ (36,907)</u>

Operating Activities

The net cash used in operating activities of \$99.8 million for the nine months ended September 30, 2024 was due to a net loss of \$102.3 million, the amortization of premiums on investments of \$3.9 million and a net cash outflow from the change in our operating assets and liabilities of \$27.8 million, which were adjusted by stock-based compensation expense of \$24.4 million, depreciation and amortization of \$4.3 million, non-cash interest expense of \$1.9 million, allowance for credit losses of \$1.8 million, non-cash lease expense of \$1.1 million, and provision for inventories of \$0.6 million. The net cash outflow from operating assets and liabilities was primarily driven by an increase in inventories, decreases in accrued expenses and other current liabilities and accounts payable due to timing of vendor payments, a decrease in accrued compensation and related benefit, an increase in accounts receivable resulting from the timing of collection and decreases in accrued warranty liability and operating lease liabilities. The net cash outflow from operating assets and liabilities was partially offset by a decrease in prepaid expenses and other assets and an increase in deferred revenue due to growth in our business.

Investing Activities

The net cash used in investing activities of \$4.2 million for the nine months ended September 30, 2024 was due to the purchases of short-term investment securities of \$150.5 million and the purchases of property and equipment of \$0.9 million, which was partially offset by the maturities of short-term investment securities of \$147.1 million.

Financing Activities

The net cash provided by financing activities of \$68.8 million for the nine months ended September 30, 2024 was due to the net proceeds of \$66.5 million from borrowings under the SLR Term Loan Facility and the proceeds from employee exercises of stock options and ESPP purchases.

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 2023 Annual Report.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Our market risks related to interest rate and foreign currency exchange rates are described in Part II Item 7A, "Quantitative and Qualitative Disclosures About Market Risk", of our 2023 Annual Report. Our exposure to market risks has not changed materially since December 31, 2023.

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 Securities Exchange Act of 1934, as amended (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 2023 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, 2024 (Q1 2024 Quarterly Report) and June 30, 2024 (Q2 2024 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 2023 Annual Report, as updated by our Q1 2024 Quarterly Report and Q2 2024 Quarterly Report, except as set forth below. The risks described in our 2023 Annual Report, Q1 2024 Quarterly Report and Q2 2024 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.

We may not be able to maintain the listing of our common stock on Nasdaq, which could adversely affect our liquidity and the trading volume and market price of our common stock.

Our common stock is listed on The Nasdaq Global Select Market, which imposes continued listing requirements with respect to listed securities, including a minimum bid price requirement.

On September 23, 2024, we received notice from the Listing Qualifications staff of The Nasdaq Stock Market LLC (“Nasdaq”) that, because the closing bid price for our common stock had fallen below \$1.00 per share for 30 consecutive trading days, we no longer complied with the minimum bid price requirement for continued listing on the Nasdaq Global Select Market under Nasdaq Listing Rule 5450(a)(1). In accordance with Nasdaq listing rules, we have an initial compliance period of 180 calendar days, or until March 24, 2025, to regain compliance with the minimum bid price requirement. To regain compliance, the closing bid price of our common stock must meet or exceed \$1.00 per share for a minimum of 10 consecutive trading days prior to March 24, 2025. If we do not regain compliance by March 24, 2025, we may be eligible for an additional 180 calendar day compliance period if we apply to transfer the listing of our common stock to the Nasdaq Capital Market and meet the continued listing requirement for the market value of our publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the minimum bid price requirement, and provide written notice of our intention to cure the minimum bid price deficiency during the second compliance period. As part of its review process, Nasdaq will make a determination as to whether it believes we will be able to cure this deficiency. If Nasdaq staff determines that we will not be able to cure the deficiency, or if we are otherwise not eligible for such additional compliance period, Nasdaq will provide notice that our common stock will be subject to delisting. We would have the right to appeal any determination to delist our common stock, and our common stock would remain listed on the Nasdaq Global Select Market until the appeal process is complete.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement, otherwise maintain compliance with other applicable Nasdaq listing rules, or be successful in appealing any delisting determination. If Nasdaq delists our common stock, it is unlikely that we will be able to list our common stock on another national securities exchange and, as a result, we expect our securities would be quoted on an over-the-counter market. If this were to occur, we and our stockholders could face significant adverse consequences, including limited availability of market quotations and analyst coverage for our common stock, and reduced liquidity for trading of our securities, all of which would likely reduce the market price of our common stock. In addition, our common stock could be considered a “penny stock,” which will require brokers trading in our common stock to adhere to more stringent rules and possibly result in reduced trading activity in the secondary trading market for our common stock. Delisting could result in additional adverse consequences including reduced ability to issue additional securities or obtain additional financing on terms acceptable to us, or at all, as well as the potential loss of confidence of our customers, suppliers and employees, any of which could harm our business and future prospects. Even the perception that we are at heightened risk of delisting could also result in certain of the above these consequences, which could negatively impact the market price and trading volume of our common stock, and harm our stockholders and our business.

Litigation and other legal proceedings may adversely affect our business.

From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, on August 29, 2024 and October 18, 2024, two

purported stockholder class action lawsuits were filed against the Company, our Chief Executive Officer and our Chief Financial Officer, in the U.S. District Court for the Northern District of California alleging that the defendants violated federal securities laws by making false or misleading statements about our 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 our revenue growth. The second lawsuit additionally names our former Chief Financial Officer as a defendant. For further information, see the section entitled “Litigation” in Note 6, Commitments and Contingencies, to our unaudited condensed financial statements included in this Quarterly Report. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers’ confidence and reduce long-term demand for Tablo, even if the regulatory or legal action is unfounded or not material to our operations.

The terms of our credit agreement require us to meet certain operating and financial covenants, place restrictions on our operating and financial flexibility and subject us to interest rate risk, and our ability to access additional borrowings is subject to us achieving certain net revenue milestones and obtaining lenders’ credit approval.

We entered into the SLR Credit Facilities on November 3, 2022, which provide for (i) up to \$250.0 million of term loans pursuant to the SLR Loan Agreement and (ii) up to a \$50.0 million asset-based revolving credit facility pursuant to the SLR Revolving Credit Agreement. We have already borrowed \$200.0 million of term loans, the full amount available under certain borrowing limitations that limit the maximum principal amount outstanding under the SLR Credit Facilities. In addition, additional borrowings under the SLR Credit Facilities are subject to us achieving certain net revenue milestones and/or obtaining lenders’ credit approval. As a result, we cannot rely on further borrowings under the SLR Credit Facilities to fund our operations. In addition, principal amounts outstanding under each of the SLR Term Loan Facility and the SLR Revolver accrue interest at variable interest rates tied to SOFR. As a result, our borrowings under the facilities are subject to interest rate risk. An adverse change in interest rates for our borrowings would increase our borrowing costs which may restrict our access to capital in the future and, ultimately, could adversely affect our financial condition and results of operations. See the section titled “Management’s Discussion and Analysis of Financial Condition and Results of Operations – Liquidity and Capital Resources – Debt Obligations – SLR Debt Financing.”

The SLR Credit Facility Agreements contain customary representations and warranties and customary affirmative and negative covenants, including, among others, requirements as to financial reporting (including the timely delivery of audited financial statements together with an unqualified report from our independent registered accountants thereon) and insurance and restrictions on our ability to dispose of our business or property, to change our 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 our property or to pay any dividends or other distributions on capital stock. Accordingly, the terms may restrict our current and future operations, particularly our ability to respond to certain changes in our business or industry or take future actions. In addition, the SLR Credit Facility Agreements also include a financial covenant that, beginning with the fiscal quarter ending December 31, 2023, requires us to either (i) maintain certain levels of cash and cash equivalents in accounts subject to control agreements in favor of Agent and ABL Lender of at least the sum of (a) 50% of the outstanding obligations under the SLR Term Loan Facility and (b) the amount of the Company’s accounts payable that have not been paid within 120 days from the invoice date thereof or (ii) generate net product and product related revenue in excess of specified amounts and maintain gross profit margins in excess of specified percentages, in each case, for applicable measuring periods. If we fail to comply with any covenants, payments or other terms of either SLR Credit Facility Agreement, our agent or lender, as applicable, could declare an event of default, which would give it the right to declare all borrowings outstanding, together with accrued and unpaid interest and fees, to be immediately due and payable. In addition, our agent or lender, as applicable, would have the right to proceed against the assets we provided as collateral pursuant to the applicable SLR Credit Facility Agreement. If the debt under either SLR Credit Facility Agreement was accelerated, we may not have sufficient cash or be able to sell sufficient assets to repay this debt, which would harm our business and financial condition.

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.

During the period covered by this report, none of the Company's directors or officers has adopted or terminated a Rule 10b5-1 trading arrangement or a non-Rule 10b5-1 trading arrangement (each as defined in Item 408 of Regulation S-K under the Exchange Act).

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
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	Form of Series A Warrant Agreement #1	S-1	333-248225	4.3	August 21, 2020
4.4	Form of Series A Warrant Agreement #2	S-1	333-248225	4.4	August 21, 2020
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, 2024, 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 6, 2024

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

November 6, 2024

By: /s/ Nabeel Ahmed
Nabeel Ahmed
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.
