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 March 31, 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	**20-0514392**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
3052 Orchard Dr. San Jose, California	**95134**
(Address of principal executive offices)	**(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, 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	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
Emerging growth company	☐		

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 May 3, 2024, the registrant had 51,722,375 shares of common stock, $0.001 par value per share, outstanding.

Table of Contents

PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 32,176	$ 68,509
Short-term investments	194,743	134,815
Accounts receivable, net	36,478	32,980
Inventories	55,839	49,215
Prepaid expenses and other current assets	6,155	5,700
Total current assets	325,391	291,219
Restricted cash	3,329	3,329
Property and equipment, net	11,953	13,273
Operating lease right-of-use assets	5,029	5,375
Other assets	540	605
Total assets	$ 346,242	$ 313,801
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 6,773	$ 5,827
Accrued compensation and related benefits	14,248	19,005
Accrued expenses and other current liabilities	11,968	13,459
Accrued warranty liability	3,200	3,712
Deferred revenue, current	12,839	11,727
Operating lease liabilities, current	1,642	1,593
Total current liabilities	50,670	55,323
Accrued interest	1,319	896
Deferred revenue	186	101
Operating lease liabilities	4,054	4,482
Term loans	196,813	130,113
Total liabilities	253,042	190,915
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 March 31, 2024 and December 31, 2023	—	—
Common stock, $0.001 par value; 300,000 shares authorized as of March 31, 2024 and December 31, 2023; 51,702 and 50,317 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	52	50
Additional paid-in capital	1,095,097	1,084,515
Accumulated other comprehensive income (loss)	(258)	68
Accumulated deficit	(1,001,691)	(961,747)
Total stockholders' equity	93,200	122,886
Total liabilities and stockholders' equity	$ 346,242	$ 313,801

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 March 31,	
	2024	**2023**
Revenue:		
Product revenue	$ 20,428	$ 27,779
Service and other revenue	7,740	5,688
Total revenue	28,168	33,467
Cost of revenue:		
Cost of product revenue	12,581	20,817
Cost of service and other revenue	7,372	6,222
Total cost of revenue	19,953	27,039
Gross profit	8,215	6,428
Operating expenses:		
Research and development	12,635	13,793
Sales and marketing	21,048	24,333
General and administrative	11,444	11,787
Total operating expenses	45,127	49,913
Loss from operations	(36,912)	(43,485)
Interest income and other income, net	3,098	2,648
Interest expense	(5,968)	(2,942)
Loss before provision for income taxes	(39,782)	(43,779)
Provision for income taxes	162	192
Net loss	$ (39,944)	$ (43,971)
Net loss per share, basic and diluted	$ (0.78)	$ (0.90)
Shares used in computing net loss per share, basic and diluted	50,901	48,783

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	
	2024	**2023**
Net loss	$ (39,944)	$ (43,971)
Other comprehensive income (loss):		
Unrealized gain (loss) on available-for-sale securities	(326)	451
Comprehensive loss	$ (40,270)	$ (43,520)

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	Accumulated Other Comprehensive	Accumulated	Total Stockholders
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
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

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	Accumulated Other Comprehensive	Accumulated	Total Stockholders
	Shares	Amount	Capital	Income (Loss)	Deficit	Equity
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

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

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

	Three Months Ended March 31,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (39,944)	$ (43,971)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	8,203	8,538
Depreciation and amortization	1,460	1,384
Non-cash lease expense	346	295
Non-cash interest expense	607	463
Accretion (amortization) of discount (premium) on investments, net	(1,577)	(1,550)
Provision for inventories	450	870
Other non-cash items	(1)	(18)
Changes in operating assets and liabilities:		
Accounts receivable	(3,497)	(6,224)
Inventories	(6,981)	2,873
Prepaid expenses and other assets	(400)	569
Accounts payable	945	1,475
Accrued compensation and related benefits	(4,462)	(7,100)
Accrued expenses and other current liabilities	(1,367)	(2,337)
Accrued warranty liability	(512)	(51)
Deferred revenue	1,197	341
Operating lease liabilities	(379)	(313)
Net cash used in operating activities	(45,912)	(44,756)
Cash flows from investing activities:		
Purchases of property and equipment	(354)	(810)
Purchases of investment securities	(98,652)	(68,147)
Maturities of investment securities	39,975	71,600
Net cash (used in) provided by investing activities	(59,031)	2,643
Cash flows from financing activities:		
Proceeds from stock option exercises and ESPP purchases	2,086	5,277
Proceeds from issuance of term loans, net of issuance costs	66,524	—
Net cash provided by financing activities	68,610	5,277
Net decrease in cash, cash equivalents and restricted cash	(36,333)	(36,836)
Cash, cash equivalents and restricted cash as of beginning of period	71,838	76,533
Cash, cash equivalents and restricted cash as of end of period	$ 35,505	$ 39,697
Supplemental cash flow disclosures:		
Cash paid for income taxes	$ 256	$ 201
Cash paid for interest	$ 4,924	$ 2,479
Cash paid for amounts included in the measurement of operating lease liabilities	$ 379	$ 313
Supplemental non-cash investing and financing activities:		
Capital expenditures included in accounts payable and accrued expenses	$ 37	$ 55
Transfer of inventories to property and equipment	$ 93	$ —

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

Outset Medical, Inc.
Notes to 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 three months ended March 31, 2024 and 2023, the Company incurred a net loss of $39.9 million and $44.0 million, respectively. As of March 31, 2024, the Company had an accumulated deficit of $1.0 billion.

As of March 31, 2024, the Company had cash, cash equivalents, restricted cash, and short-term investments of $230.2 million. The Company is subject to certain covenants limiting or restricting its ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. 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. 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-month period are also unaudited. The results of operations for the three months ended March 31, 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 FASB issued 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 is 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, the 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 is 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 March 31,	
	2024	**2023**
Consoles	$ 9,210	$ 18,863
Consumables	11,218	8,916
Total product revenue	20,428	27,779
Service and other revenue	7,740	5,688
Total revenue	$ 28,168	$ 33,467

Remaining Performance Obligations and Contract Liabilities

As of March 31, 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 $13.0 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 $0.2 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 months ended March 31, 2024, the Company recognized $5.6 million of previously deferred revenue.

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):

		March 31, 2024			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 12,303	$ —	$ —	$ 12,303
Short-term investments:					
U.S. Treasury securities	Level 1	120,584	9	(236)	120,357
U.S. government-sponsored enterprises debt securities	Level 2	20,226	8	(33)	20,201
Corporate debt	Level 2	38,850	21	(24)	38,847
Commercial paper	Level 2	15,341	—	(3)	15,338
Total cash equivalents and short-term investments		$ 207,304	$ 38	$ (296)	$ 207,046

		December 31, 2023			
	Valuation Hierarchy	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		$ 179,629	$ 143	$ (74)	$ 179,698

As of March 31, 2024, the remaining contractual maturities for available-for-sale securities were one month to fifteen months.

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

	March 31, 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
U.S. Treasury securities	$ 104,003	$ (225)	$ 4,971	$ (10)	$ 108,974	$ (235)
U.S. government-sponsored enterprises	7,910	(22)	9,917	(11)	17,827	(33)
Corporate debt	31,089	(28)	—	—	31,089	(28)
Total	$ 143,002	$ (275)	$ 14,888	$ (21)	$ 157,890	$ (296)

	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	18,757	(22)	8,488	(16)	27,245	(38)
Corporate debt	11,291	(4)	—	—	11,291	(4)
Total	$ 38,464	$ (42)	$ 26,413	$ (32)	$ 64,877	$ (74)

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 March 31, 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 months ended March 31, 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 March 31, 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):

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

Inventories

Inventories consist of the following (in thousands):

	March 31, 2024	December 31, 2023
Raw materials	$ 22,322	$ 18,706
Work in process	11,693	8,728
Finished goods	21,824	21,781
Total inventories	$ 55,839	$ 49,215

Accrued Expenses and Other Current Liabilities

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

	March 31, 2024	December 31, 2023
Inventory	$ 3,400	$ 3,395
Research and development expenses	530	1,050
Professional services	1,257	1,153
Customer rebates	1,555	2,100
Other	5,226	5,761
Total accrued expenses and other current liabilities	$ 11,968	$ 13,459

6. Commitments and Contingencies

Litigation

From time to time, the Company may become involved in 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. The Company is not presently a party to any legal proceedings that, if determined adversely to the Company, would individually or taken together have a material adverse effect on its business, results of operations, financial condition or cash flows.

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 Loan

Term loan consists of the following (in thousands):

	March 31, 2024	December 31, 2023
Principal of term loans	$ 200,000	$ 133,476
Unamortized debt discount	(3,187)	(3,363)
Term loans, noncurrent	$ 196,813	$ 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. As of March 31, 2024, the Company borrowed an aggregate principal amount of $200.0 million under the SLR Term Loan Facility. If the Company achieves a certain net revenue milestone, calculated on a trailing six-month basis (First Revenue Milestone), on or before June 30, 2024 and the Additional Tranche (as defined below) under the SLR Revolver has been approved, the Company will be permitted to borrow up to an additional $50.0 million under the SLR Credit Facilities (i.e., a maximum amount of $250.0 million). If the Company achieves a subsequent additional net revenue milestone, calculated on a trailing six-month basis (Second Revenue Milestone), on or before June 30, 2025 and obtains lenders' credit approval, the Company will be permitted to further borrow up to an additional $50.0 million under the SLR Credit Facilities (i.e., a maximum amount of $300.0 million).

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 available subject to lenders' credit approval and the achievement of the Second Revenue Milestone on or before June 30, 2025. The Term C Loans will 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% (10.47% as of March 31, 2024), payable monthly in arrears. The Company is permitted to make interest-only payments on the Term Loans through November 30, 2026, which

may be extended at the Company's option to May 31, 2027; provided that the Company meets the First Revenue Milestone. 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. No amounts were outstanding under the SLR Revolver as of March 31, 2024.

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. 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, in each case with certain exceptions. The agreements also include a financial covenant that, beginning with the fiscal quarter ending 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 March 31, 2024, 2,476,000 shares were reserved for future issuance under the 2020 Equity Incentive Plan (2020 Plan).

Employee Share Purchase Plan (ESPP)

As of March 31, 2024, 931,000 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 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 March 31,	
	2024	**2023**
Cost of revenue	$ 265	$ 358
Research and development	2,332	2,615
Sales and marketing	1,459	2,598
General and administrative	4,147	2,967
Total stock-based compensation expense	$ 8,203	$ 8,538

9. Income Taxes

For each of the three months ended March 31, 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 Months Ended March 31,	
	2024	**2023**
Stock options to purchase common stock	1,841	2,427
Restricted stock units	4,461	2,645
Performance stock units	257	101
Shares committed under ESPP	26	22
Warrant to purchase common stock	63	63
Total	6,648	5,258

11. Workforce reduction

In order to improve operational efficiencies, reduce operating expenses and streamline its overall organizational structure, the Company recently implemented two organizational restructurings. At the beginning of the fourth quarter of 2023, the Company began a workforce reduction which was substantially completed by the end of 2023, incurring restructuring charges of $2.5 million in the fourth quarter of 2023 for employee severance and other termination benefits. In May 2024, the Company implemented an additional workforce reduction plan (the May 2024 workforce reduction plan) and, as a result, estimated and recognized restructuring charges of $3.0 million in the first quarter of 2024 for employee severance and other termination benefits. Restructuring accruals are based upon management estimates at the time and are subject to change depending upon changes in facts and circumstances subsequent to the date the original liability was recorded.

The following table sets forth severance and related benefits charges related to the May 2024 workforce reduction plan included in the accompanying condensed statements of operations (in thousands):

	Three Months Ended March 31, 2024
Cost of revenue	$ 308
Research and development	1,152
Sales and marketing	946
General and administrative	550
Total	$ 2,956

For the three months ended March 31, 2024, changes in liabilities resulting from the restructuring accruals, which were recorded in accrued compensation and related benefits on the accompanying condensed balance sheet, were as follows (in thousands):

Balance as of December 31, 2023	$ 854
Charges	2,956
Payments	781
Balance as of March 31, 2024	$ 3,029

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 Annual Report on Form 10-K for the fiscal year ended December 31, 2023. 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 cartridge, and services, which generates significant total revenue over the life of Tablo console. Our total revenue was $28.2 million and $33.5 million for the three months ended March 31, 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 49% of our total full-time employees as of March 31, 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 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 efforts to further evolve our commercial infrastructure and sales processes to support the growth of our business in the acute care market.

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 our ability to further evolve our commercial infrastructure and sales processes as we scale our business in the home market.

Gross Margin

Our ability to expand our gross margins depends on: first, our ability to reduce the cost of Tablo consoles; second, our ability to continue to sell Tablo cartridges, services, and accessories for Tablo consoles; and third, our ability to reduce the cost of service. Over the past three 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. 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, our ability to expand gross margins will 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. Our ability to expand gross margins depends on our ability to successfully execute these strategies.

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 into 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, rising costs and other financial pressures, whether due to general macroeconomic conditions 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 months ended March 31, 2024 and 2023 (in thousands):

	Three Months Ended March 31,	
	2024	2023
Revenue:		
Product revenue	$ 20,428	$ 27,779
Service and other revenue	7,740	5,688
Total revenue	28,168	33,467
Cost of revenue:		
Cost of product revenue	12,581	20,817
Cost of service and other revenue	7,372	6,222
Total cost of revenue	19,953	27,039
Gross profit	8,215	6,428
Operating expenses:		
Research and development	12,635	13,793
Sales and marketing	21,048	24,333
General and administrative	11,444	11,787
Total operating expenses	45,127	49,913
Loss from operations	(36,912)	(43,485)
Interest income and other income, net	3,098	2,648
Interest expense	(5,968)	(2,942)
Loss before provision for income taxes	(39,782)	(43,779)
Provision for income taxes	162	192
Net loss	$ (39,944)	$ (43,971)

Comparison of the Three Months Ended March 31, 2024 and 2023

Revenue

	Three Months Ended March 31,		Change	
(dollars in thousands)	2024	2023	$	%
Revenue:				
Product revenue	$ 20,428	$ 27,779	$ (7,351)	(26)%
Service and other revenue	7,740	5,688	2,052	36%
Total revenue	$ 28,168	$ 33,467	(5,299)	(16)%

Product revenue decreased by $7.4 million or 26% for the three months ended March 31, 2024 as compared to the same period in the prior year. This decrease was driven by a $9.7 million decrease in console revenue which was partially offset by a $2.3 million increase in consumable revenue due to the growth in our console installed base.

Service and other revenue increased by $2.1 million or 36% for the three months ended March 31, 2024 as compared to the same period in the prior year. This increase was primarily due to services associated with the growth in our console installed base.

Gross Profit and Gross Margin

	Three Months Ended March 31,		Change	
(dollars in thousands)	2024	2023	$	%
Gross profit and gross margin:				
Gross profit	$ 8,215	$ 6,428	$ 1,787	28%
Gross margin	*29.2* %	*19.2* %		

Gross profit increased by $1.8 million or 28% for the three months ended March 31, 2024 as compared to the same period in the prior year. Gross margin improved by 10.0 percentage points for the three months ended March 31, 2024, as compared to the same period in the prior year. This improvement in gross profit and gross margin was primarily driven by a higher mix of consumable and service and other revenue, both of which had improved gross margin year over year. The higher consumable gross margin resulted from lower cost per unit and a higher average selling price for consumables. Such improvement was partially offset by a lower average selling price for consoles.

Operating Expenses

(dollars in thousands)	Three Months Ended March 31, 2024	2023	Change $	Change %
Operating expenses:				
Research and development	$ 12,635	$ 13,793	$ (1,158)	(8)%
Sales and marketing	21,048	24,333	(3,285)	(14)%
General and administrative	11,444	11,787	(343)	(3)%
Total operating expenses	$ 45,127	$ 49,913	(4,786)	(10)%

Research and development expenses decreased by $1.2 million or 8% for the three months ended March 31, 2024, as compared to the same period in the prior year. This 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. These decreases were partially offset by the severance and related charges recorded in the current year.

Sales and marketing expenses decreased by $3.3 million or 14% for the three months ended March 31, 2024 as compared to the same period in the prior year. The decrease was primarily driven by an overall decrease in compensation-related and stock-based compensation expense, travel, consulting and marketing expenses resulting from our cost reduction efforts implemented in the fourth quarter of 2023. These decreases were partially offset by the severance and related charges recorded in the current year and higher freight expenses due to higher volume in consumable sales.

General and administrative expenses decreased by $0.3 million or 3% for the three months ended March 31, 2024 as compared to the same period in the prior year. This decrease was primarily due to an overall decrease in consulting expenses, infrastructure costs, and compensation-related expense resulting from our cost reduction efforts implemented in the fourth quarter of 2023. Our insurance costs also decreased as compared to the prior year. These decreases were partially offset by an increase in stock-based compensation expense and the severance and related charges recorded in the current year.

Other Income (Expense), Net

(dollars in thousands)	Three Months Ended March 31, 2024	2023	Change $	Change %
Other income (expenses), net:				
Interest income and other income, net	$ 3,098	$ 2,648	$ 450	17%
Interest expense	(5,968)	(2,942)	(3,026)	103%
Total other expenses, net	$ (2,870)	$ (294)	(2,576)	876%

The increase in interest income and other income, net for the three months ended March 31, 2024 as compared to the same period in the prior year was driven by higher interest rates.

The increase in interest expense for the three months ended March 31, 2024 as compared to the same period in the prior year was due to the increase in interest rate and a higher outstanding balance under the SLR Term Loan Facility in 2024.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2024, we had cash, cash equivalents, restricted cash and short-term investments of $230.2 million.

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.

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, including through refinancing 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 reevaluate 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 will be subject to an increase in our interest expense which may negatively affect our cash flow. We also are subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. 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):

	Three Months Ended March 31,	
	2024	**2023**
Net cash (used in) provided by:		
Operating activities	$ (45,912)	$ (44,756)
Investing activities	(59,031)	2,643
Financing activities	68,610	5,277
Net decrease in cash, cash equivalents and restricted cash	$ (36,333)	$ (36,836)

Operating Activities

The net cash used in operating activities of $45.9 million for the three months ended March 31, 2024 was due to a net loss of $39.9 million, the amortization of premiums on investments of $1.6 million and a net cash outflow from the change in our operating assets and liabilities of $15.5 million, which were adjusted by stock-based compensation expense of $8.2 million, depreciation and amortization of $1.5 million, non-cash interest expense of $0.6 million, provision for inventories of $0.5 million, and non-cash lease expense of $0.3 million. The net cash outflow from operating assets and liabilities was primarily driven by an increase in inventory, a decrease in accrued compensation and related benefits primarily due to annual cash bonus payouts for 2023, an increase in accounts receivable resulting from the timing of collection, and a decrease in accrued expenses and other current liabilities. The net cash outflow from operating assets and liabilities was partially offset by an increase in deferred revenue and accounts payable.

Investing Activities

The net cash used in investing activities of $59.0 million for the three months ended March 31, 2024 was due to the purchases of short-term investment securities of $98.7 million and the purchases of property and equipment of $0.4 million, which was partially offset by the maturities of short-term investment securities of $40.0 million.

Financing Activities

The net cash provided by financing activities of $68.6 million for the three months ended March 31, 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, "Qualitative 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 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.

From time to time we may become involved in 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. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows.

Item 1A. Risk Factors.

You should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 2023 Annual 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, except as set forth below. The risks described in our 2023 Annual 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.

While we recently resumed distribution of TabloCart with Prefiltration following the FDA's clearance of our 510(k) submission, we may continue to experience disruptions as a result of the warning letter and our prior distribution pause on TabloCart with Prefiltration.

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 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.

While we believe we have now taken appropriate measures to fully address the matters raised in the Warning Letter, we cannot guarantee that the FDA will be fully satisfied with our response or the remedial measures we have taken, or that we will not receive other warning letters or be subject to other FDA enforcement actions in the future.

Moreover, our business and operations have experienced disruptions as a result of the Warning Letter and our pause on the distribution of TabloCart with Prefiltration, including reputational harm, customer uncertainty regarding the matters addressed in the Warning Letter, diversion of management's time and attention, as well as adverse impacts on our bookings and revenues. For example, beginning in the third quarter of 2023 and continuing through the first quarter of 2024, we observed more customers than we anticipated choosing to defer their Tablo console purchasing and installation until TabloCart with Prefiltration became available again, and we also experienced marketplace confusion in relation to the Warning Letter, particularly regarding Tablo's range of therapeutic modalities. These factors, combined with other macroeconomic factors, served to elongate our sales cycle and the timing of delivery and installations which, in turn, had an adverse impact on our bookings and revenues for the second half of 2023 and the first quarter of 2024. Even as we resume distribution of TabloCart with Prefiltration following its FDA clearance, if we are unable to sufficiently recover from these disruptions and any reputational harm at the levels or on the timeframes we anticipate, we may experience further disruptions which could include adverse impacts on our backlog, our ability to expand customer relationships or attract new customers, as well as reduced demand for TabloCart and/or, potentially, Tablo. Any of these factors could materially and adversely affect our results of operations, financial condition and growth prospects.

If we or our suppliers fail to comply with ongoing FDA or other foreign regulatory authority requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Even though we have obtained 510(k) clearance for Tablo, it and any other product for which we obtain clearance or approval, and the manufacturing processes, post-market surveillance, post-approval clinical data and promotional activities for such product, will be subject to continued regulatory review, oversight, requirements, and periodic inspections by the FDA and other domestic and foreign regulatory bodies. In particular, we and our suppliers are required to comply with FDA's Quality System Regulation (QSR) and other regulations enforced outside the United States which cover the manufacture of our products and the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, storage and shipping of medical devices. The QSR requires that each manufacturer establish a quality systems program by which the manufacturer monitors the manufacturing process and maintains records that show compliance with FDA regulations and the manufacturer's written specifications and procedures relating to the devices. QSR compliance is necessary to receive and maintain FDA clearance or approval to market new and existing products. Regulatory bodies, such as the FDA, enforce the QSR and other regulations through periodic audits and inspections. The failure by us or one of our suppliers to comply with applicable statutes and regulations administered by the FDA and other regulatory bodies, or the failure to timely and adequately respond to any adverse inspectional observations or product safety issues, could result in, among other things, any of the following enforcement actions:

- FDA untitled letters, FDA Form 483s, FDA warning letters, it has come to our attention letters, fines, injunctions, consent decrees and civil penalties;
- unanticipated expenditures to address or defend such actions
- customer notifications for repair, replacement, refunds;
- recall, detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying our requests for 510(k) clearance or PMA approval of new products or modified products;
- withdrawal of 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approval for our products; or
- criminal prosecution.

For example, the FDA conducted their first quality system inspection of our San Jose, California facility which concluded in February 2023. At completion, the FDA issued a Form FDA-483 identifying four inspectional observations. We provided our response plan to the FDA in March 2023 and have since completed the associated remediation workstreams to fully address these observations. We continue to provide the FDA with updates as to the status of these 483-related workstreams. Although we believe we are in material compliance with the QSR and have addressed the observations identified in the Form-483, there is no guarantee that subsequent inspections of our facility by the FDA or other regulatory authorities will not result in similar observations with respect to our quality system, which could adversely affect our business.

The FDA can also publish Safety Communications or Letters to Health Care Providers when the agency becomes aware of new issues involving a specific product or, or more broadly, a product family. These communications are posted on the FDA's website and describe the FDA's analysis of a current issue and provide specific regulatory approaches and clinical recommendations for patient management. If any of these actions were to occur it would harm our reputation and cause our product sales and profitability to suffer and may prevent us from generating revenue. Furthermore, our key component suppliers may not currently be or may not

continue to be in compliance with all applicable regulatory requirements which could result in our failure to produce our products on a timely basis and in the required quantities, if at all.

In addition, we are required to conduct costly post-market testing and surveillance to monitor the safety or effectiveness of our products, and we must comply with medical device reporting requirements, including the reporting of adverse events and malfunctions related to our products.

Later discovery of previously unknown problems with our products, including unanticipated adverse events or adverse events of unanticipated severity or frequency, manufacturing problems, or failure to comply with regulatory requirements such as QSR, may result in changes to labeling, restrictions on such products or manufacturing processes, withdrawal of the products from the market, voluntary or mandatory recalls, a requirement to repair, replace or refund the cost of any medical device we manufacture or distribute, fines, suspension of regulatory approvals, product seizures, injunctions or the imposition of civil or criminal penalties which would adversely affect our business, operating results and prospects.

For example, in May 2022, the FDA published a Letter to Healthcare Providers entitled "Potential Risk of Exposure to Toxic Compounds When Using Certain Hemodialysis Machines Manufactured by Fresenius Medical Care – Letter to Health Care Providers." In that communication, the agency stated that it is evaluating the potential risk of exposure to non-dioxin-like (NDL) polychlorinated biphenyl acids (PCBAs) and NDL polychlorinated biphenyls (PCBs) with certain hemodialysis machines marketed in the United States. The FDA stated that the source of the NDL PCBAs and NDL PCBs is from the silicone tubing used as a part of the hydraulics in those machines and the dialysate lines. Although Tablo was not the subject of the FDA's Letter to Healthcare Providers, the FDA reached out to Outset regarding the tubing used in Tablo. In a series of discussions with the FDA, the agency requested that we conduct a targeted analysis and a screening analysis on the tubing currently used in Tablo. We aligned with the FDA on testing and screening protocols prior to conducting our analysis of the data. In parallel, we filed a 510(k) application, and received subsequent 510(k) clearance from the FDA for, PCB-free silicone tubing in December 2023. As previously disclosed, in early March 2024, we proactively initiated a workstream to replace the remaining few silicone segments in new and existing Tablo consoles with the new, PCB-free, silicone tubing, and this action is well underway. In April 2024, we were notified by the FDA that it has designated this correction as a Class 1 recall, similar to the classification they have made with respect to other manufacturers whose medical devices contain NDL PCBAs and NDL PCBs with the potential of patient exposure. While we are continuing with the field correction as planned, and this recall does not at this time involve the removal of Tablo from the marketplace, the recall may nevertheless damage our reputation with customers and harm our financial results and business. Furthermore, these negative impacts could be exacerbated if the FDA publishes a safety notice specific to Tablo or subjects us to other enforcement actions.

We are highly dependent on our senior management team and key personnel, and our business could be harmed if we are unable to attract and retain personnel necessary for our success in a cost-effective manner.

We are highly dependent on our senior management, including our chief executive officer, Leslie Trigg, and other key personnel. Our success will depend on our ability to retain senior management and to attract and retain qualified personnel in the future, including sales and marketing professionals, scientists, clinical specialists, engineers and other highly skilled personnel and to integrate current and additional personnel in all departments. The loss of members of our senior management, sales and marketing professionals, scientists, clinical and regulatory specialists and engineers could result in delays in product development and harm our business. If we are not successful in attracting and retaining highly qualified personnel, or if we are unable to do so in a cost-effective manner, it would have a material adverse effect on our business, financial condition, and results of operations.

Competition for skilled personnel in our market is intense and has recently intensified further due to industry trends in many areas where our employees are located. Further, the increased availability of hybrid or remote working arrangements has expanded the pool of companies that can compete for our employees and employment candidates. Such competition may limit our ability to hire and retain highly qualified personnel on acceptable terms, or at all. We may experience higher compensation costs to retain senior management and experienced personnel that may not be offset by improved productivity. Moreover, in order to improve operational efficiencies, reduce operating expenses, and streamline our overall organizational structure, we substantially completed a restructuring of our organization in the fourth quarter of 2023, and we implemented an additional workforce reduction plan in May 2024. These recent restructurings, as well as any future restructurings, may adversely affect our ability to attract and retain employees. To induce valuable employees to remain at our company, in addition to salary and cash incentives, we have issued and may continue to issue equity awards that vest over time. The value to employees of equity awards that vest over time may be significantly affected by movements in our stock price that are beyond our control and may at any time be insufficient to counteract more lucrative offers from other companies. Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Our employment arrangements with our employees provide for at-will employment, which means that any of our employees could leave our employment at any time, with or without notice. We also do not maintain “key man” insurance policies on the lives of these individuals or the lives of any of our other employees.

Our customers are facing financial pressures including capital budget constraints, staffing shortages and increased costs, that have had, and may continue to have, a negative impact on our revenue.

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 further 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 into 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. Moreover, in February 2024, Change Healthcare, a large provider of healthcare payment systems, experienced a cyberattack on its information technology systems, causing disruptions to healthcare providers across the United States, including financial impacts such as reduced reimbursements and cash flow. We believe several of our customers experiencing these disruptions deferred both Tablo console and treatment purchases until their cash flow normalized, adversely impacting our revenues for the first quarter of 2024. 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.

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

None.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Form of Amended and Restated Certificate of Incorporation of Outset Medical, Inc.	S-1/A	333-248225	3.1	September 9, 2020
3.2	Form of Amended and Restated Bylaws of Outset Medical, Inc.	S-1/A	333-248225	3.2	September 9, 2020
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
10.1†^	Outset Medical, Inc. 2020 Equity Incentive Plan , as amended and restated	10-K	001-39513	10.4	February 21, 2024
10.2*	Amendment to Manufacturing Services Agreement by and between TACNA Services, Inc. and Outset Medical, Inc. effective as of February 12, 2024				
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.

† Indicates a management contract or compensatory plan or arrangement.

Portions of the exhibit have been or will be excluded because it is both not material and is the type of information that the registrant treats as private or confidential.

^ Included herein solely to correct an incorrect hyperlink in the Exhibit Index to the Company's Annual Report on Form 10-K for the year ended December 31, 2023.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Outset Medical, Inc.

Date: May 8, 2024

By: /s/ Leslie Trigg

Leslie Trigg
President and Chief Executive Officer
(*Principal Executive Officer*)

Date: May 8, 2024

By: /s/ Nabeel Ahmed

Nabeel Ahmed
Chief Financial Officer
(*Principal Financial and Accounting Officer*)

Exhibit 10.2

***Portions of this exhibit have been excluded because it is both (i) not material and (ii) the type of information that the Registrant both customarily and actually treats as private and confidential.**

TACNA Services, Inc.

MANUFACTURING SERVICE AGREEMENT

Client: Outset Medical
ANNEX "A"
(Service Fee Schedule)
Effective February 12, 2024

Number of Employees	Total Paid Hours	Weekly Fee Per Paid Hour ($/Hour)
0 - 100	0 – 4,800	$[***]
101 - 200	4,801 – 9,600	$[***]
201 - 300	9,601 – 14,000	$[***]
301 - 400	14,001 – 19,200	$[***]
401 - 500	19,201 – 24,000	$[***]
501 -600	24,001 – 28,800	$[***]
601 - 700	28,801 – 33,600	$[***]

Prices are increased annually based on changes in San Diego CPI for the most recent 12 months published as of the November preceding the change with the next change effective January 1, 2025

This serves as an amendment to the Manufacturing Services Agreement ("MSA") between Outset Medical, Inc ("Outset"). and TACNA Services, Inc. ("TACNA"). In the coming years Outset anticipates growth to over [***] people ([***] weekly hours) and beyond in its Mexico operation. With such growth TACNA and Outset have agreed to lower pricing associated with higher tiers of growth in exchange for increasing the defined contact term through a minimum of February 12, 2027, after which the 120-day notice clause of article B.15 of that contract provision shall apply.

Outset agrees to meet with TACNA as needed to confidentially review cash flows, the path to profitability, and accumulated severance risk as needed, but no less frequently than annually.

Agreed to among the Parties by signing below using facsimile signatures:

TACNA SERVICES, INC.	Outset Medical, Inc.
By:	By:
/s/ Ross Baldwin	/s/ Kulwant Sandhu
Ross K. Baldwin	Print Name: Kulwant Sandhu
President	Title: VP, Integrated Supply Chain
Dated: 2/21/2024	Dated: 2/15/2024

Exhibit 31.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Leslie Trigg, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Outset Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2024

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

Exhibit 31.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Nabeel Ahmed, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Outset Medical, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 8, 2024

By: /s/ Nabeel Ahmed
Nabeel Ahmed
Chief Financial Officer
(*Principal Financial Officer*)

Exhibit 32.1

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 March 31, 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.

May 8, 2024 By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(*Principal Executive Officer*)

May 8, 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.