UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2023

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 November 2, 2023, the registrant had 50,204,570 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
(in thousands, except per share amounts)

	September 30, 2023	December 31, 2022
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 36,297	$ 73,222
Short-term investments	157,701	214,280
Accounts receivable, net	35,493	28,070
Inventories	48,257	51,476
Prepaid expenses and other current assets	6,026	6,597
Total current assets	283,774	373,645
Restricted cash	3,329	3,311
Property and equipment, net	13,774	15,876
Operating lease right-of-use assets	5,713	6,117
Other assets	961	1,166
Total assets	$ 307,551	$ 400,115
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,880	$ 603
Accrued compensation and related benefits	21,544	21,519
Accrued expenses and other current liabilities	12,160	16,227
Accrued warranty liability	4,068	3,620
Deferred revenue, current	10,828	8,662
Operating lease liabilities, current	1,544	1,318
Total current liabilities	53,024	51,949
Accrued interest	680	113
Deferred revenue	99	151
Operating lease liabilities	4,901	5,576
Term loan	96,784	96,336
Total liabilities	155,488	154,125
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of September 30, 2023 and December 31, 2022	—	—
Common stock, $0.001 par value; 300,000 shares authorized as of September 30, 2023 and December 31, 2022; 50,173 and 48,465 shares issued and outstanding as of September 30, 2023 and December 31, 2022, respectively	50	48
Additional paid-in capital	1,075,413	1,035,456
Accumulated other comprehensive loss	(253)	(564)
Accumulated deficit	(923,147)	(788,950)
Total stockholders' equity	152,063	245,990
Total liabilities and stockholders' equity	$ 307,551	$ 400,115

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue:				
Product revenue	$ 23,531	$ 21,739	$ 80,640	$ 67,024
Service and other revenue	6,831	6,022	19,229	16,344
Total revenue	30,362	27,761	99,869	83,368
Cost of revenue:				
Cost of product revenue	16,837	19,632	59,866	60,460
Cost of service and other revenue	6,368	3,793	18,715	10,348
Total cost of revenue	23,205	23,425	78,581	70,808
Gross profit	7,157	4,336	21,288	12,560
Operating expenses:				
Research and development	16,076	13,059	44,775	37,411
Sales and marketing	24,720	22,276	74,038	65,851
General and administrative	11,815	10,000	34,892	30,493
Total operating expenses	52,611	45,335	153,705	133,755
Loss from operations	(45,454)	(40,999)	(132,417)	(121,195)
Interest income and other income, net	2,573	805	7,889	1,384
Interest expense	(3,213)	(567)	(9,258)	(1,470)
Loss before provision for income taxes	(46,094)	(40,761)	(133,786)	(121,281)
Provision for income taxes	86	20	411	231
Net loss	$ (46,180)	$ (40,781)	$ (134,197)	$ (121,512)
Net loss per share, basic and diluted	$ (0.93)	$ (0.85)	$ (2.72)	$ (2.54)
Shares used in computing net loss per share, basic and diluted	49,913	48,129	49,364	47,835

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Net loss	$ (46,180)	$ (40,781)	$ (134,197)	$ (121,512)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	140	21	311	(750)
Comprehensive loss	$ (46,040)	$ (40,760)	$ (133,886)	$ (122,262)

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

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

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

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

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

	Common Stock		Additional Paid-in Capital	Accumulated Other Comprehensive Loss	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
Balance as of December 31, 2021	47,241	$ 47	$ 1,000,212	$ (184)	$ (625,994)	$ 374,081
Issuance of common stock through employee stock purchase plan	55	—	2,063	—	—	2,063
Issuance of common stock for settlement of RSUs	88	—	—	—	—	—
Stock option exercises	328	1	1,659	—	—	1,660
Stock-based compensation expense	—	—	5,006	—	—	5,006
Unrealized loss on available-for-sale securities	—	—	—	(465)	—	(465)
Net loss	—	—	—	—	(36,892)	(36,892)
Balance as of March 31, 2022	47,712	$ 48	$ 1,008,940	$ (649)	$ (662,886)	$ 345,453
Issuance of common stock for settlement of RSUs	52	—	—	—	—	—
Stock option exercises	233	—	1,042	—	—	1,042
Stock-based compensation expense	—	—	7,414	—	—	7,414
Unrealized loss on available-for-sale securities	—	—	—	(306)	—	(306)
Net loss	—	—	—	—	(43,839)	(43,839)
Balance as of June 30, 2022	47,997	$ 48	$ 1,017,396	$ (955)	$ (706,725)	$ 309,764
Issuance of common stock through employee stock purchase plan	138	—	2,139	—	—	2,139
Issuance of common stock for settlement of RSUs	49	—	—	—	—	—
Stock option exercises	111	—	530	—	—	530
Stock-based compensation expense	—	—	7,430	—	—	7,430
Unrealized gain on available-for-sale securities	—	—	—	21	—	21
Net loss	—	—	—	—	(40,781)	(40,781)
Balance as of September 30, 2022	48,295	$ 48	$ 1,027,495	$ (934)	$ (747,506)	$ 279,103

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

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

	Nine Months Ended September 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (134,197)	$ (121,512)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	29,536	19,850
Depreciation and amortization	4,364	3,900
Non-cash lease expense	919	826
Non-cash interest expense	1,377	426
Accretion (amortization) of discount (premium) on investments, net	(5,099)	1,081
Provision for inventories	672	1,617
Other non-cash items	247	26
Changes in operating assets and liabilities:		
Accounts receivable	(7,564)	3,079
Inventories	2,607	(17,692)
Prepaid expenses and other assets	440	728
Accounts payable	2,251	(575)
Accrued compensation and related benefits	25	(5,675)
Accrued expenses and other current liabilities	(4,108)	2,476
Accrued warranty liability	447	(248)
Deferred revenue	2,114	1,315
Operating lease liabilities	(962)	(844)
Net cash used in operating activities	(106,931)	(111,222)
Cash flows from investing activities:		
Purchases of property and equipment	(2,387)	(6,216)
Purchases of investment securities	(121,262)	(168,615)
Maturities of investment securities	183,250	160,284
Net cash provided by (used in) investing activities	59,601	(14,547)
Cash flows from financing activities:		
Proceeds from stock option exercises and employee stock purchase plan purchases	10,423	7,433
Payment of deferred financing costs	—	(135)
Net cash provided by financing activities	10,423	7,298
Net decrease in cash, cash equivalents and restricted cash	(36,907)	(118,471)
Cash, cash equivalents and restricted cash as of beginning of period	76,533	215,659
Cash, cash equivalents and restricted cash as of end of period	$ 39,626	$ 97,188
Supplemental cash flow disclosures:		
Cash paid for income taxes	$ 403	$ 334
Cash paid for interest	$ 1,836	$ 1,044
Cash paid for amounts included in the measurement of operating lease liabilities	$ 962	$ 844
Supplemental non-cash investing and financing activities:		
Capital expenditures included in accounts payable and accrued expenses	$ 207	$ 556
Right-of-use assets obtained in exchange for operating lease liabilities	$ 514	$ —

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

1. Description of Business

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

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. During the nine months ended September 30, 2023 and 2022, the Company incurred a net loss of $134.2 million and $121.5 million, respectively. As of September 30, 2023, the Company had an accumulated deficit of $923.1 million.

As of September 30, 2023, the Company had cash, cash equivalents, and short-term investments of $194.0 million, which are available to fund future operations, and restricted cash of $3.3 million, for a total cash, cash equivalents, restricted cash, and short-term investments balance of $197.3 million. 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 and currently available from the debt financing described in Note 7, will be sufficient to meet its anticipated needs for at least the next 12 months from the issuance date of the accompanying condensed financial statements.

Basis of Presentation

The accompanying condensed financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, that are necessary for the fair statement of the Company's financial position, results of operations, comprehensive loss, and cash flows for the interim periods presented. The financial data and the other financial information disclosed in these notes to the condensed financial statements related to the three- and nine-month periods are also unaudited. The results of operations for the three and nine months ended September 30, 2023 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, 2022 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, 2022, which are included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2022 filed with the Securities and Exchange Commission (SEC) on February 13, 2023 (2022 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 Adopted Accounting Pronouncements

In June 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires an entity to utilize a new impairment model known as the current expected credit loss (CECL) model to estimate its lifetime "expected credit loss" and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments, including but not limited to available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. The Company adopted ASU 2016-13 during the first quarter of fiscal year 2023. The adoption did not have a material impact on the Company's financial statements. Please see the description of the Company's "Credit Losses" accounting policy in the "Significant Accounting Policies" section below.

Significant Accounting Policies

With the exception of the change from accounting for credit losses as a result of the adoption of ASU 2016-13, there have been no new or material changes to the Company's significant accounting policies as described in its 2022 Annual Report that have had a material impact on the Company's condensed financial statements and related notes.

Credit Losses

Accounts receivable. The allowance for doubtful accounts is based on the Company's assessment of the Company's best estimate of the amount of credit losses in customer accounts. The Company regularly reviews the allowance by considering factors such as existing contractual payment terms, historical experience, credit quality, the age of the accounts receivable balances, and current economic conditions that may affect a customer's ability to pay. The allowance for doubtful accounts was not significant as of September 30, 2023 and December 31, 2022.

Available-for-sale debt securities. The Company primarily holds U.S. government-sponsored enterprises debt securities, corporate debt securities, commercial paper, U.S. Treasury securities and money market funds. The Company regularly reviews the securities in an unrealized loss position and evaluates the current expected credit loss by considering factors such as historical experience, market data, 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. The Company segments its portfolio based on the underlying risk profiles of the securities and has a zero-loss expectation for U.S. treasury and U.S. government-sponsored enterprises debt securities. The basis for this assumption is that these securities have consistently high credit ratings by rating agencies, have a long history with no credit losses, are explicitly guaranteed by a sovereign entity, which can print its own currency, and are denominated in a currency that is routinely held by central banks, used in international commerce, and commonly viewed as a reserve currency. Additionally, all of the Company's investments in corporate debt securities are in securities with high-quality credit ratings, which have historically experienced low rates of default.

3. Revenue and Deferred Revenue

Disaggregation of Revenue

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Consoles	$ 12,506	$ 14,950	$ 51,053	$ 46,229
Consumables	11,025	6,789	29,587	20,795
Total product revenue	23,531	21,739	80,640	67,024
Service and other revenue	6,831	6,022	19,229	16,344
Total revenue	$ 30,362	$ 27,761	$ 99,869	$ 83,368

For the three and nine months ended September 30, 2023, $0.1 million and $0.2 million of consoles revenue were from console operating lease arrangements, compared to $0.6 million and $1.9 million for the three and nine months ended September 30, 2022.

Remaining Performance Obligations and Contract Liabilities

As of September 30, 2023, 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 $10.9 million, which is recorded as deferred revenue on the Company's condensed balance sheets. Of that amount, $10.8 million will be recognized as revenue during the next 12 months and $0.1 million thereafter.

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition. Revenue under these agreements is recognized over the related service period. During the three and nine months ended September 30, 2023, the Company recognized $1.7 million and $7.9 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):

		September 30, 2023			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 27,188	$ —	$ —	$ 27,188
Short-term investments:					
U.S. Treasury securities	Level 1	57,301	—	(134)	57,167
U.S. government-sponsored enterprises debt securities	Level 2	48,520	2	(116)	48,406
Corporate debt	Level 2	2,963	—	(5)	2,958
Commercial paper	Level 2	49,170	—	—	49,170
Total cash equivalents and short-term investments		$ 185,142	$ 2	$ (255)	$ 184,889

		December 31, 2022			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 42,834	$ —	$ —	$ 42,834
U.S. government-sponsored enterprises debt securities	Level 2	7,965	—	—	7,965
Short-term investments:					
U.S. Treasury securities	Level 1	133,473	9	(447)	133,035
U.S. government-sponsored enterprises debt securities	Level 2	26,404	42	(14)	26,432
Corporate debt	Level 2	29,831	—	(154)	29,677
Commercial paper	Level 2	25,136	—	—	25,136
Total cash equivalents and short-term investments		$ 265,643	$ 51	$ (615)	$ 265,079

As of September 30, 2023, the remaining contractual maturities for available-for-sale securities were one month to thirteen months.

The following tables present the breakdown of the available-for-sale debt securities with unrealized losses as of September 30, 2023, and December 31, 2022 (in thousands):

	September 30, 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	$ 44,208	$ (126)	6,968	(8)	$ 51,176	$ (134)
U.S. government-sponsored enterprises	38,514	(116)	—	—	38,514	(116)
Corporate debt	2,958	(5)	—	—	2,958	(5)
Total	$ 85,680	$ (247)	$ 6,968	$ (8)	$ 92,648	$ (255)

	December 31, 2022					
	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	$ 95,499	$ (343)	$ 12,895	$ (103)	$ 108,394	$ (446)
U.S. government-sponsored enterprises	16,464	(14)	—	—	16,464	(14)
Corporate debt	21,480	(142)	8,196	(13)	29,676	(155)
Total	$ 133,443	$ (499)	$ 21,091	$ (116)	$ 154,534	$ (615)

The unrealized losses on the Company's available-for-sale debt securities were caused by interest rate increases. The contractual terms of those investments do not permit the issuer to settle the securities at a price less than the amortized cost basis of the investments. As of September 30, 2023, the Company does not intend to sell the investments, and it is not more likely than not that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be at maturity. Additional factors considered in determining the treatment of unrealized losses include the financial condition and near-term prospects of the investee, the extent of the loss related to the credit of the issuer, and the expected cash flows from the security. For the three and nine months ended September 30, 2023 and 2022, the Company did not recognize credit loss related to available-for-sales debt securities.

5. Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

As of September 30, 2023 and December 31, 2022, the restricted cash balance of $3.3 million, respectively, was related to collateral for the Company's building leases in San Jose, CA and Tijuana, Mexico.

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

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

Inventories

Inventories consist of the following (in thousands):

	September 30, 2023	December 31, 2022
Raw materials	$ 21,989	$ 20,623
Work in process	8,968	9,086
Finished goods	17,300	21,767
Total inventories	$ 48,257	$ 51,476

Accrued Expenses and Other Current Liabilities

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

	September 30, 2023	December 31, 2022
Inventory	$ 3,345	$ 5,585
Research and development expenses	914	908
Professional services	1,079	1,261
Customer rebates	2,166	1,364
Other	4,656	7,109
Total accrued expenses and other current liabilities	$ 12,160	$ 16,227

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):

	September 30, 2023	December 31, 2022
Principal of term loan	$ 100,000	$ 100,000
Unamortized debt discount	(3,216)	(3,664)
Term loan, noncurrent	$ 96,784	$ 96,336

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: (i) a 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) an 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. The Company is permitted to borrow up to $200.0 million under the SLR Credit Facilities on the Closing Date. 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 $250.0 million under the SLR Credit Facilities. 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 borrow up to $300.0 million under the SLR Credit Facilities.

SLR Term Loan Facility

Pursuant to the terms and conditions of the SLR Loan Agreement, 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) one or more term loans (in minimum increments of $20.0 million each) in the aggregate of up to $100.0 million (each, a Term B Loan) and (iii) one or more term loans in the aggregate of up to $50.0 million (each, a Term C Loan). 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 A Loan was funded on the Closing Date. The Term B Loan(s) are available for funding until August 22, 2024. The Term C Loan(s) are available subject to the lenders' credit approval and the achievement of the Second Revenue Milestone on or before June 30, 2025. The Term C Loan 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% (10.48% as of September 30, 2023), 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 fee in the amount of $750,000 in respect of the Term B Loan(s), to be due and payable upon the earliest to occur of (a) the funding of the first Term B Loan, (b) December 20, 2023 and (c) the prepayment of the Term 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.

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 continuing 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 Company has also agreed to a financial covenant whereby, 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 (or maintain gross profit margins) in excess of specified amounts (or percentages) 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 certain 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.

In November 2022, the Company borrowed $100.0 million under the Term A Loan on the Closing Date and incurred debt issuance costs of $3.8 million which were recorded as a direct deduction from the Term A Loan on the balance sheets and are being recognized as non-cash interest expense over the term of the loan using the effective interest method, along with the final payment fee. The facility fees of $0.9 million related to the Term B Loan and the Initial Revolver Commitment were recorded as deferred financing costs and are being recognized as non-cash interest expense over their respective commitment period using straight-line method.

8. Equity Incentive Plan

Equity Incentive Plans

As of September 30, 2023, 4,644,000 shares were reserved for future issuance under the 2020 Equity Incentive Plan (2020 Plan).

Employee Share Purchase Plan (ESPP)

As of September 30, 2023, 1,204,000 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. 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.

In 2022, the Company issued 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. These PSUs are earned and vest over performance and vesting periods extending through 2024 based on achievement against two metrics: (1) an operational metric tied to the number of patients treating at home on Tablo as of the end of 2023, with 50% of earned units vesting after certification of the achievement level following the end of 2023 and the remaining 50% of earned units vesting at the end of 2024 (performance-based vesting conditions, referred to as the 2022 Home PSUs) and (2) the Company's relative total stockholder return (relative TSR) over a two-year performance period as compared to companies in a pre-determined index of medical device companies, with 100% of earned units vesting at the end of 2024 (market-based vesting conditions, referred to as the 2022 Relative TSR PSUs). In 2023, the Company issued additional PSUs (2023 Home PSUs and 2023 Relative TSR PSUs) and RSUs to its CEO, other executive officers and certain other senior leaders under terms that are substantially the same except that the performance and vesting periods extend through 2025.

The 2023 target for the 2022 Home PSUs was approved by the Compensation Committee in early 2023. Therefore, the grant date and the fair value for these 2022 Home PSUs were established and the associated expense is being recognized over the remaining service period.

The 2024 target for the 2023 Home PSUs is expected to be determined and approved by the Compensation Committee in late 2023 or early 2024. Given such target has not yet been established, the grant date for these 2023 Home PSUs will only be established when the Compensation Committee approves and the Company communicates the target to the award recipients, which will then trigger the service inception date, the fair value of the awards, and the associated expense recognition period. Therefore, no expense is expected to be recognized for these 2023 Home PSUs until the grant date is established.

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

9. Income Taxes

For each of the three and nine months ended September 30, 2023 and 2022, 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 September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Stock options to purchase common stock	1,978	2,739	1,978	2,739
Restricted stock units	2,760	1,511	2,760	1,511
Performance stock units	95	30	95	30
Shares committed under ESPP	42	32	42	32
Warrant to purchase common stock	63	63	63	63
Total	4,938	4,375	4,938	4,375

11. Subsequent Event

Early in the fourth quarter of 2023, the Company began restructuring its organization to better align its talent, organizational design and spending in support of its most critical strategies while also streamlining its overall cost structure. In connection with this restructuring, which is expected to be substantially completed during the fourth quarter of 2023, the Company expects to incur approximately $2.5 million of severance expense in the fourth quarter of 2023. These charges are termination benefits and are all cash charges.

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 2022 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. 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. 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, the Tablo® Hemodialysis System 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 and treatments remotely, perform patient and population analytics, and automate clinical recordkeeping, while also enabling us to release features and enhancements through over-the-air updates. Tablo's connectedness also allows it to continually stream more than 500,000 device performance data points after every treatment. We use this data, in conjunction with our diagnostic and predictive algorithms, to determine failure types and, in some instances, predict failures before they occur. 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. To demonstrate the cost advantages of Tablo in the home setting, we are continuing to collect additional patient clinical experience and outcomes data.

In May 2022, we implemented a shipment hold on the distribution and marketing of Tablo for use in the home environment pending the FDA's review and clearance of a 510(k) application we submitted for changes made since the device's original March 2020 clearance. In late July 2022, the FDA cleared our 510(k) application of Tablo for patient use in the home and we resumed marketing and shipping Tablo for home use.

On July 6, 2023, we received a warning letter (the "Warning Letter") from the FDA that raised two observations. The first observation asserts that certain content reviewed by the FDA and found on our website promotes continuous renal replacement therapy (CRRT), a modality outside of the current indications for the Tablo Hemodialysis System. The second observation asserts that TabloCart with Prefiltration requires prior 510(k) clearance for marketing authorization. TabloCart with Prefiltration is an accessory to the Tablo System 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 been effectively addressed with two actions. First, 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. Second, we submitted to the FDA a 510(k) application for TabloCart with Prefiltration on September 8, 2023. In addition, we submitted responses to the FDA in July, August and September 2023, and believe we have taken appropriate measures to resolve the matters raised in the Warning Letter. We have not identified any safety issues with TabloCart with Prefiltration. While we remain committed to fully cooperating with the FDA to expeditiously and completely resolve the Warning Letter, we cannot guarantee that the FDA will be satisfied with our response or the remedial measures we have taken, nor can we give any assurances as to the timing of the resolution of such matters, including the clearance of the 510(k) application and our resumption of distribution of TabloCart with Prefiltration.

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 consoles at existing customer sites. In addition, our field service team provides maintenance services and product support to Tablo customers. Our field sales and service teams represent 45% of our total full-time employees as of September 30, 2023. 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.

We generate revenue primarily from the initial sale of Tablo consoles and recurring sales of consumables, including the Tablo cartridges, which generates significant total revenue over the life of the console. We generate additional recurring revenue via annual service contracts and shipping and handling charged to customers. Our total revenue was $30.4 million and $27.8 million for the three months ended September 30, 2023 and 2022, respectively, and $99.9 million and $83.4 million for the nine months ended September 30, 2023 and 2022, respectively.

Historically, we have financed our operations and capital expenditures primarily through sales of redeemable convertible preferred stock and common stock, revenue from sales, and debt financing. Since our inception, we have incurred net losses in each year. For the three months ended September 30, 2023 and 2022, we incurred net losses of $46.2 million and $40.8 million, respectively, and for the nine months ended September 30, 2023 and 2022, we incurred net losses of $134.2 million and $121.5 million, respectively. As of September 30, 2023, we had an accumulated deficit of $923.1 million. We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term.

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 (IDNs) 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 expeditiously resolve the Warning Letter and overcome the adverse impact in the field from the Warning Letter and our distribution pause on 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 and health systems 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

We are continuing to execute a well-defined strategy designed to expand gross margins. First, during 2021, we fully insourced console manufacturing at our own manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA Services (TACNA). Second, during 2022, we moved production of a majority of Tablo cartridges from our contract manufacturer in Southeast Asia to a contract manufacturer in Mexico, which helped us achieve cost reductions through lower freight costs and mitigate against global supply chain challenges. At the end of 2022, we initiated production of Tablo cartridges in-house at our manufacturing facility in Mexico which we operate in collaboration with TACNA in an effort to help further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations. Third, we will continue to use our design, engineering and manufacturing capabilities to help further advance and improve the efficiency of our manufacturing processes and lower our costs of production. Fourth, we will continue to utilize our cloud-based data system, as well as enhanced product performance, to help drive down the cost of service. Our ability to grow our business will depend in part on our ability to control the average selling prices of our products and services, including by selling higher-margin hardware and software accessories and consumables. In addition, our gross margin will further depend on the aforementioned and other measures to control the costs of our products. Likewise, it will be important that we effectively manage the costs of generating our service revenue.

Impacts of Macroeconomic Factors

Global macroeconomic conditions, including global supply chain disruptions, inflationary pressures, rising interest rates, increased labor costs and labor shortages, 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, on our customers, or on our suppliers.

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, continue to disrupt the operations of certain of our third-party suppliers, resulting, in some cases, in increased lead times and higher component costs. In addition, we faced increased supply chain constraints during late 2021, notably with the transportation of Tablo cartridges from our contract manufacturing partner in Southeast Asia. As a result, we faced increased transportation and related costs associated with delivering adequate supply of Tablo treatments to our customers. During 2023, we have seen moderation in these costs. Moreover, we believe that transitioning production of a majority of Tablo cartridges during 2022 to a Mexico-based manufacturer helped us achieve cost reductions through lower freight costs, and that the initiation of the production of cartridges in-house at our manufacturing facility in Mexico at the end of 2022 helped further our long-term gross margin expansion and supply continuity strategies and improve the flexibility of our operations. However, there is no assurance that we will not continue to face supply chain constraints. Continued escalation of supply chain disruptions 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. Further, a sustained rise in material and freight costs could also unfavorably impact our operating margins and results of operations.

Moreover, healthcare providers (including our existing and prospective customers) are facing a nationwide shortage of qualified nurses and other clinical personnel due to long-term trends that were exacerbated by the recent COVID-19 pandemic. As competition for these healthcare professionals has intensified, providers are facing increased difficulties attracting and retaining skilled clinical personnel, resulting in increased costs, staffing shortages and other disruptions. 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, there is a risk that the increased costs and other disruptions caused by the shortage of dialysis nurses, technicians, other staff, and implementation resources could cause existing or prospective customers to delay continued investment in or adoption of new technologies and postpone purchasing decisions. For example, during 2022, our existing and prospective customers faced increasing staffing shortages and 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. Furthermore, while we have generally seen some stabilization in these challenging labor market dynamics in 2023 as compared to the prior year, during 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 for the third quarter of 2023, and we expect these negative impacts to continue into 2024. If our customers continue to face prolonged periods of rising interest rates, capital budget constraints, volatility, uncertainty, staffing shortages, rising costs and 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, 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. This pilot program may not be successful in achieving the objectives we intend and anticipate and ultimately, it may fail to meet our customers' expectations, any of which could harm our reputation and customer relationships. In addition, the program may not generate sufficient returns to justify our investment, or may result in unanticipated costs, which could adversely impact our operating margins and results of operations.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2023 and 2022 (in thousands):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Revenue:				
Product revenue	$ 23,531	$ 21,739	$ 80,640	$ 67,024
Service and other revenue	6,831	6,022	19,229	16,344
Total revenue	30,362	27,761	99,869	83,368
Cost of revenue:				
Cost of product revenue	16,837	19,632	59,866	60,460
Cost of service and other revenue	6,368	3,793	18,715	10,348
Total cost of revenue	23,205	23,425	78,581	70,808
Gross profit	7,157	4,336	21,288	12,560
Operating expenses:				
Research and development	16,076	13,059	44,775	37,411
Sales and marketing	24,720	22,276	74,038	65,851
General and administrative	11,815	10,000	34,892	30,493
Total operating expenses	52,611	45,335	153,705	133,755
Loss from operations	(45,454)	(40,999)	(132,417)	(121,195)
Interest income and other income, net	2,573	805	7,889	1,384
Interest expense	(3,213)	(567)	(9,258)	(1,470)
Loss before provision for income taxes	(46,094)	(40,761)	(133,786)	(121,281)
Provision for income taxes	86	20	411	231
Net loss	$ (46,180)	$ (40,781)	$ (134,197)	$ (121,512)

Comparison of the Three and Nine Months Ended September 30, 2023 and 2022

Revenue

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(dollars in thousands)	2023	2022	$	%	2023	2022	$	%
Revenue:								
Product revenue	$ 23,531	$ 21,739	$ 1,792	8%	$ 80,640	$ 67,024	$ 13,616	20%
Service and other revenue	6,831	6,022	809	13%	19,229	16,344	2,885	18%
Total revenue	$ 30,362	$ 27,761	2,601	9%	$ 99,869	$ 83,368	16,501	20%

Product revenue increased by $1.8 million or 8% for the three months ended September 30, 2023 as compared to the same period in the prior year. This increase was driven by a $4.2 million increase in consumables revenue due to growth in our console installed base, which was partially offset by a $2.4 million decrease in console revenue.

Product revenue increased by $13.6 million, or 20% for the nine months ended September 30, 2023 as compared to the same period in the prior year. This increase was driven by an $8.8 million increase in consumables revenue attributable to growth in our console installed base as well as a $4.8 million increase in console revenue.

Service and other revenue increased for the three and nine months ended September 30, 2023 as compared to the same periods in the prior year. The increase was primarily due to services associated with the growth in our console installed base, which was partially offset by the expiration of certain lease agreements.

During the third quarter of 2023, several 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 quarter. These factors related to our recent Warning Letter, our distribution pause on TabloCart with Prefiltration and certain macroeconomic impacts on our customers. We observed more customers than we anticipated choosing to defer their Tablo console purchasing and installation until TabloCart with Prefiltration becomes available again. In addition, the Warning Letter created a certain amount of marketplace confusion (exacerbated, we believe, in some cases by our competitors) particularly regarding Tablo's use in the intensive care unit (ICU). We anticipate that the negative impacts from the Warning Letter and our distribution pause will continue through at least the end of 2023. If the FDA's review of our pending 510(k) application for TabloCart with Prefiltration and the current distribution pause continues for an extended period of time, if the FDA ultimately does not grant clearance of our 510(k) application, or if we are otherwise unable to overcome the adverse impact in the field from the Warning Letter and our distribution pause for a prolonged period of time, our revenues could be materially

and adversely impacted. Finally, during 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 we expect to continue into 2024.

Gross Profit and Gross Margin

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(dollars in thousands)	2023	2022	$	%	2023	2022	$	%
Gross profit and gross margin:								
Gross profit	$ 7,157	$ 4,336	$ 2,821	65 %	$ 21,288	$ 12,560	$ 8,728	69 %
Gross margin	*23.6* %	*15.6* %			*21.3* %	*15.1* %		

Gross profit increased by $2.8 million or 65% for the three months ended September 30, 2023 as compared to the same period in the prior year. Gross margin improved by 8.0 percentage points for the three months ended September 30, 2023 as compared to the same period in the prior year. The improvements in gross profit and gross margin were primarily driven by the impact of cost reduction activities for consoles in combination with increased volume and a higher average selling price for consumables. Such improvement was partially offset by lower service gross margin primarily due to the expiration of certain lease agreements.

Gross profit increased by $8.7 million or 69% for the nine months ended September 30, 2023 as compared to the same period in the prior year. Gross margin improved by 6.2 percentage points for the nine months ended September 30, 2023 as compared to the same period in the prior year. The improvements in gross profit and gross margin were primarily driven by the impact of cost reduction activities and a higher average selling price for both consoles and consumables. Such improvement was partially offset by lower service gross margin primarily due to the expiration of certain lease agreements.

Operating Expenses

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(dollars in thousands)	2023	2022	$	%	2023	2022	$	%
Operating expenses:								
Research and development	$ 16,076	$ 13,059	$ 3,017	23 %	$ 44,775	$ 37,411	$ 7,364	20 %
Sales and marketing	24,720	22,276	2,444	11 %	74,038	65,851	8,187	12 %
General and administrative	11,815	10,000	1,815	18 %	34,892	30,493	4,399	14 %
Total operating expenses	$ 52,611	$ 45,335	7,276	16 %	$ 153,705	$ 133,755	19,950	15 %

Research and development expenses increased by $3.0 million or 23% for the three months ended September 30, 2023 as compared to the same period in the prior year. The increase was primarily due to higher headcount, resulting in increased fixed and stock-based compensation expense, higher consulting expenses and increased supplies and materials costs.

Research and development expenses increased by $7.4 million or 20% for the nine months ended September 30, 2023 as compared to the same period in the prior year. The increase was primarily due to higher headcount, resulting in increased fixed and stock-based compensation expense, increased infrastructure, supplies and materials costs, partially offset by lower consulting expenses.

Sales and marketing expenses increased by $2.4 million or 11% for the three months ended September 30, 2023 as compared to the same period in the prior year. The increase was primarily driven by higher headcount, resulting in increased fixed and stock-based compensation expense, increased infrastructure costs, higher freight expense due to increased consumable volume, and higher marketing, consulting and travel expenses.

Sales and marketing expenses increased by $8.2 million or 12% for the nine months ended September 30, 2023 as compared to the same period in the prior year. The increase was primarily driven by higher headcount, resulting in increased fixed and stock-based compensation expense, increased infrastructure costs, higher commission expense due to increased sales, higher marketing and travel expenses, and higher freight expense due to increased consumable volume, partially offset by lower consulting expenses.

General and administrative expenses increased by $1.8 million or 18% for the three months ended September 30, 2023 as compared to the same period in the prior year. The increase was primarily driven by higher headcount, resulting in increased fixed and stock-based compensation expense, and higher consulting expenses, partially offset by a decrease in insurance expense.

General and administrative expenses increased by $4.4 million or 14% for the nine months ended September 30, 2023 as compared to the same period in the prior year. The increase was primarily driven by higher headcount, resulting in increased fixed and stock-based compensation expense, higher consulting and travel expenses, and higher infrastructure costs, partially offset by a decrease in insurance expense.

Other Income (Expense), Net

(dollars in thousands)	Three Months Ended September 30, 2023	Three Months Ended September 30, 2022	Change $	Change %	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022	Change $	Change %
Other income (expenses), net:								
Interest income and other income, net	$ 2,573	$ 805	$ 1,768	220 %	$ 7,889	$ 1,384	$ 6,505	470 %
Interest expense	(3,213)	(567)	(2,646)	467 %	(9,258)	(1,470)	(7,788)	530 %
Total other expenses, net	$ (640)	$ 238	(878)	(369)%	$ (1,369)	$ (86)	(1,283)	1492 %

The increase in interest income and other income, net for the three and nine months ended September 30, 2023 as compared to the same periods in the prior year was driven by higher interest rates and a higher average short-term investments balance in 2023.

The increase in interest expense for the three and nine months ended September 30, 2023 was due to the higher interest expense and outstanding balance under the SLR Term Loan Facility in 2023 as compared to the lower interest expense and outstanding balance under our prior term loan facility with Silicon Valley Bank in 2022.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2023, we had cash, cash equivalents and short-term investments of $194.0 million, which are available to fund future operations, and restricted cash of $3.3 million, for a total cash, cash equivalents, restricted cash and short-term investments balance of $197.3 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 exercises 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 financing, 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. We are subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. We believe that our existing cash, cash equivalents and short-term investments, cash generated from sales, and proceeds received and currently available from the debt financing described in Note 7 of the accompanying condensed financial statements above, will be sufficient to meet our anticipated needs for at least the next 12 months from the issuance date of this Quarterly Report.

Cash Flows Summary

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

	Nine Months Ended September 30, 2023	Nine Months Ended September 30, 2022
Net cash (used in) provided by:		
Operating activities	$ (106,931)	$ (111,222)
Investing activities	59,601	(14,547)
Financing activities	10,423	7,298
Net decrease in cash, cash equivalents and restricted cash	$ (36,907)	$ (118,471)

Operating Activities

The net cash used in operating activities of $106.9 million for the nine months ended September 30, 2023 was due to a net loss of $134.2 million, the amortization of premiums on investments of $5.1 million and a net cash outflow from the change in our operating assets and liabilities of $4.8 million, which were adjusted by stock-based compensation expense of $29.5 million, depreciation and amortization of $4.4 million, non-cash interest expense of $1.4 million, non-cash lease expense of $0.9 million, provision for inventories of $0.7 million, and other non-cash items of $0.2 million. The net cash outflow from operating assets and liabilities was primarily driven by an increase in accounts receivable resulting from the timing of collection, and a decrease in accrued expenses and other current liabilities due to timing of vendor payments. The net cash outflow from operating assets and liabilities was partially offset by an increase in accounts payable due to timing of vendor payments, a decrease in inventories as a result of the timing of inventory purchases and our effort to optimize working capital, and an increase in deferred revenue due to growth in our business.

Investing Activities

The net cash provided by investing activities of $59.6 million for the nine months ended September 30, 2023 was due to the maturities of short-term investment securities of $183.3 million, which was partially offset by the purchases of short-term investment securities of $121.3 million and the purchases of property and equipment of $2.4 million.

Financing Activities

The net cash provided by financing activities of $10.4 million for the nine months ended September 30, 2023 was due to the proceeds from employee exercises of stock options and ESPP purchases.

Critical Accounting Policies and 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 policies and estimates as compared to the critical accounting policies and estimates disclosed in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2022 Annual Report.

Recoupment Policy

In April 2023, we adopted a recoupment (or "clawback") policy that applies to incentive compensation paid to current and certain former executive officers that was based on incorrect financial performance measures. Under the policy, if we are required to prepare an accounting restatement due to the material noncompliance of any financial reporting requirement under applicable securities laws, the Compensation Committee of our Board of Directors is required to cause us to recoup from each executive officer the excess of the incentive compensation received by such executive officer during the three-year period preceding the date on which we are required to prepare the financial restatement, based on the erroneous financial information, over the incentive compensation that would have been received by the executive if it had been calculated based on the restated financial information. The policy is intended to comply with the requirements of Securities and Exchange Commission rules and Nasdaq Stock Market (Nasdaq) listing standards implementing Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010.

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 of our 2022 Annual Report. Our exposure to market risks has not changed materially since December 31, 2022.

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 2022 Annual Report, as updated by the risk factors discussed in Part II, "Item 1A. Risk Factors" in our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2023 (Q2 2023 Quarterly Report), which could materially affect our business, financial position, or future results of operations. There have been no material changes to the risk factors described in our 2022 Annual Report, as updated by our Q2 2023 Quarterly Report, except as set forth below. The risks described in our 2022 Annual Report and Q2 2023 Quarterly Report, as updated below, are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial, may also arise and materially impact our business. If any of these risks occur, our business, results of operations and financial condition could be materially and adversely affected and the trading price of our common stock could decline.

We are subject to risks related to the warning letter we recently received from the FDA and the pause we recently implemented on the distribution of TabloCart with Prefiltration.

As previously disclosed in our 2022 Annual Report, the FDA issued an FDA Form-483 identifying four inspectional observations resulting from an FDA inspection of our San Jose, California facility that concluded on February 10, 2023. We provided our response plan to the FDA in March 2023, and have since completed the associated remediation workstreams to fully address these observations.

On July 6, 2023, we received a warning letter (the "Warning Letter") from the FDA that raised two observations. The first observation asserts that certain content reviewed by the FDA and found on our website promotes CRRT, a modality outside of the current indications for the Tablo Hemodialysis System. The second observation asserts that TabloCart with Prefiltration requires prior 510(k) clearance for marketing authorization. TabloCart with Prefiltration is an accessory to the Tablo System 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 been effectively addressed with two actions. First, 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. Second, we submitted to the FDA a 510(k) application for TabloCart with Prefiltration on September 8, 2023. In addition, we submitted responses to the FDA in July, August and September 2023, and believe we have taken appropriate measures to resolve the matters raised in the Warning Letter.

While we remain committed to fully cooperating with the FDA to expeditiously and completely resolve the Warning Letter, we cannot guarantee that the FDA will be satisfied with our response or the remedial measures we have taken, nor can we give any assurances as to the timing of the resolution of such matters, including the clearance of the 510(k) application and our resumption of distribution of TabloCart with Prefiltration. Failure to promptly and fully address the matters raised in the Warning Letter to the FDA's satisfaction or to comply with FDA regulations in general could result in further regulatory and enforcement actions being initiated by the FDA. These actions may include, among other things, additional inspections, requirements to implement additional remedial measures, recommending or requiring that we cease manufacturing or producing TabloCart with Prefiltration or that we withdraw or recall the product from the marketplace, until clearance is obtained (which may not happen in a timely manner or at all), as well as product seizures, injunctions, civil monetary penalties, fines, or criminal prosecution. In addition, although we have paused distribution of TabloCart with Prefiltration pending the FDA's review and clearance of the submitted 510(k) application, the FDA could specifically mandate that we do so, which would result in the resumption of such distribution being outside of our sole control. Any such actions could materially and adversely disrupt and harm our business, reputation, financial condition, results of operations and future growth.

In addition, while we have submitted a 510(k) application for TabloCart with Prefiltration, we cannot predict with certainty when the FDA will complete its review of our application, whether the FDA will ultimately grant clearance of our application, or when we will resume distribution of the product. Based on the results of the FDA's review, we may be required to take additional actions, which may include making changes to the product, temporarily withdrawing or recalling TabloCart with Prefiltration until clearance is obtained (which may not happen in a timely manner or at all), and/or we may be subject to other enforcement actions or proceedings and litigation, any of which could materially and adversely disrupt and harm our business and future growth.

Moreover, even if we are able to expeditiously and definitively resolve the Warning Letter, we will continue to incur incremental expenses relating to doing so, and we have experienced and expect to continue to experience related disruptions to our business, including reputational harm, customer uncertainty regarding the matters addressed in the Warning Letter and diversion of management's time and attention. Furthermore, our business and operations have experienced and may continue to experience disruptions as a result of our pause on the distribution of TabloCart with Prefiltration, including reputational harm and adverse impacts on our bookings and revenues, and 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. For example, during the third quarter of 2023, we observed more customers than we anticipated choosing to defer their Tablo console purchasing and installation until TabloCart with Prefiltration becomes available again, and we also experienced marketplace confusion in relation to the Warning Letter (exacerbated, we believe, in some cases by our competitors), particularly regarding Tablo's use in the ICU. These factors, among others discussed in the risk factor below, 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 third quarter of 2023. We anticipate that the negative impacts from the Warning Letter and our distribution pause will continue through at least the end of 2023. Moreover, these risks and adverse impacts will be exacerbated if the FDA's review of our pending 510(k) application for TabloCart with Prefiltration and the current distribution pause (or any mandated distribution pause by the FDA) continues for an extended period of time, or if the FDA ultimately does not grant clearance of our 510(k) application.

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.

Healthcare providers (including our existing and prospective customers) are facing a nationwide shortage of qualified nurses and other clinical personnel due to long-term trends that were exacerbated by the recent COVID-19 pandemic. As competition for these healthcare professionals has intensified, providers are facing increased difficulties attracting and retaining skilled clinical personnel, resulting in increased costs, staffing shortages, and other disruptions. There is a risk that the increased costs and other disruptions caused by the shortage of dialysis nurses, technicians and other staff could cause existing or prospective customers to delay continued investment in or adoption of new technologies and postpone purchasing decisions. For example, during 2022, our existing and prospective customers faced increasing staffing shortages and 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. Furthermore, while we have generally seen some stabilization in these challenging labor market dynamics in 2023 as compared to the prior year, during 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 for the third quarter of 2023, and we expect these negative impacts to continue into 2024. 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, 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. This pilot program may not be successful in achieving the objectives we intend and anticipate and ultimately, it may fail to meet our customers' expectations, any of which could harm our reputation and customer relationships. In addition, the program may not generate sufficient returns to justify our investment, or may result in unanticipated costs, which could 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.

During the period covered by this Quarterly Report, none of our directors or officers adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K, except as follows:

- On August 7, 2023, D. Keith Grossman, a member of our Board of Directors and our Lead Independent Director, adopted a Rule 10b5-1 trading plan arrangement that is intended to satisfy the affirmative defense of Rule 10b5-1(c) for the sale of up to 133,870 shares of our common stock. The plan will expire on August 7, 2024, or on such earlier date on which all of the trades thereunder have been executed or all trading orders relating to such trades have expired.

Item 6. Exhibits.

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Form of Amended and Restated Certificate of Incorporation of Outset Medical, Inc.	S-1/A	333-248225	3.1	September 9, 2020
3.2	Form of Amended and Restated Bylaws of Outset Medical, Inc.	S-1/A	333-248225	3.2	September 9, 2020
4.1	Form of Common Stock Certificate	S-1/A	333-248225	4.1	September 9, 2020
4.2	Amended and Restated Registration Rights Agreement	S-1	333-248225	4.2	August 21, 2020
4.3	Form of Series A Warrant Agreement #1	S-1	333-248225	4.3	August 21, 2020
4.4	Form of Series A Warrant Agreement #2	S-1	333-248225	4.4	August 21, 2020
31.1*	Certification of Principal Executive Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
31.2*	Certification of Principal Financial Officer Pursuant to Rules 13a-14(a) and 15d-14(a) of the Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
32.1*	Certification of Principal Executive Officer and Principal Financial Officer Pursuant to 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	Inline XBRL Instance Document – the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101)				

* Filed herewith.

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: November 7, 2023

By: /s/ Leslie Trigg

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

Date: November 7, 2023

By: /s/ Nabeel Ahmed

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

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: November 7, 2023

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: November 7, 2023

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 September 30, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to her/his knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations the Company.

November 7, 2023 By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(*Principal Executive Officer*)

November 7, 2023 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.