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 June 30, 2022

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 July 27, 2022, the registrant had 48,007,301 shares of common stock, $0.001 par value per share, outstanding.

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PART I—FINANCIAL INFORMATION

Item 1. Financial Statements.

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

	June 30, 2022	December 31, 2021
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 75,497	$ 182,348
Short-term investments	186,565	157,140
Accounts receivable, net	24,627	25,600
Inventories	53,689	39,185
Prepaid expenses and other current assets	5,399	5,529
Total current assets	345,777	409,802
Restricted cash	33,311	33,311
Property and equipment, net	15,245	12,964
Operating lease right-of-use assets	6,687	7,231
Other assets	216	156
Total assets	$ 401,236	$ 463,464
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,753	$ 1,763
Accrued compensation and related benefits	15,795	24,948
Accrued expenses and other current liabilities	23,261	13,789
Accrued warranty liability	3,444	3,704
Deferred revenue, current	7,752	6,340
Operating lease liabilities, current	1,235	1,151
Term loan, current	1,000	—
Total current liabilities	55,240	51,695
Accrued interest, noncurrent	960	721
Deferred revenue, noncurrent	205	312
Operating lease liabilities, noncurrent	6,261	6,893
Term loan, noncurrent	28,806	29,762
Total liabilities	91,472	89,383
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 June 30, 2022 and December 31, 2021	—	—
Common stock, $0.001 par value; 300,000 shares authorized as of June 30, 2022 and December 31, 2021; 47,997 and 47,241 shares issued and outstanding as of June 30, 2022 and December 31, 2021, respectively	48	47
Additional paid-in capital	1,017,396	1,000,212
Accumulated other comprehensive loss	(955)	(184)
Accumulated deficit	(706,725)	(625,994)
Total stockholders' equity	309,764	374,081
Total liabilities and stockholders' equity	$ 401,236	$ 463,464

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 June 30,		Six Months Ended June 30,	
	2022	**2021**	**2022**	**2021**
Revenue:				
Product revenue	$ 19,621	$ 20,628	$ 45,285	$ 38,838
Service and other revenue	5,436	4,588	10,322	9,294
Total revenue	25,057	25,216	55,607	48,132
Cost of revenue:				
Cost of product revenue	17,718	22,077	40,828	42,654
Cost of service and other revenue	3,557	2,087	6,555	4,137
Total cost of revenue	21,275	24,164	47,383	46,791
Gross profit	3,782	1,052	8,224	1,341
Operating expenses:				
Research and development	13,521	8,032	24,352	15,602
Sales and marketing	23,198	13,204	43,575	26,353
General and administrative	10,784	9,722	20,493	18,968
Total operating expenses	47,503	30,958	88,420	60,923
Loss from operations	(43,721)	(29,906)	(80,196)	(59,582)
Interest income and other income, net	459	164	579	276
Interest expense	(481)	(431)	(903)	(853)
Loss before provision for income taxes	(43,743)	(30,173)	(80,520)	(60,159)
Provision for income taxes	96	35	211	74
Net loss	$ (43,839)	$ (30,208)	$ (80,731)	$ (60,233)
Net loss per share, basic and diluted	$ (0.92)	$ (0.66)	$ (1.69)	$ (1.36)
Shares used in computing net loss per share, basic and diluted	47,882	45,680	47,686	44,228

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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Net loss	$ (43,839)	$ (30,208)	$ (80,731)	$ (60,233)
Other comprehensive loss:				
Unrealized loss on available-for-sale securities	(306)	(20)	(771)	(29)
Comprehensive loss	$ (44,145)	$ (30,228)	$ (81,502)	$ (60,262)

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 Income (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**

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 Income (Loss)	Accumulated Deficit	Total Stockholders Equity
	Shares	Amount				
Balance as of December 31, 2020	42,722	$ 43	$ 822,624	$ 1	$ (494,059)	$ 328,609
Issuance of common stock through employee stock purchase plan	80	—	1,838	—	—	1,838
Stock option exercises	86	—	380	—	—	380
Stock-based compensation expense	—	—	5,852	—	—	5,852
Unrealized loss on available-for-sale securities	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	(30,025)	(30,025)
Balance as of March 31, 2021	42,888	$ 43	$ 830,694	$ (8)	$ (524,084)	$ 306,645
Issuance of common stock upon follow-on public offering, net of issuance costs	2,946	3	149,082	—	—	149,085
Issuance of common stock for settlement of RSUs	1	—	—	—	—	—
Stock option exercises	390	—	1,723	—	—	1,723
Stock-based compensation expense	—	—	3,937	—	—	3,937
Unrealized loss on available-for-sale securities	—	—	—	(20)	—	(20)
Net loss	—	—	—	—	(30,208)	(30,208)
Balance as of June 30, 2021	46,225	$ 46	$ 985,436	$ (28)	$ (554,292)	$ 431,162

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

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

	Six Months Ended June 30,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (80,731)	$ (60,233)
Adjustments to reconcile net loss to net cash used in operating activities:		
Stock-based compensation expense	12,420	9,789
Depreciation and amortization	2,586	2,553
Non-cash lease expense	544	501
Non-cash interest expense	282	282
Accretion of discount on investments, net	1,035	435
Provision for inventories	808	325
Other non-cash items	29	5
Changes in operating assets and liabilities:		
Accounts receivable	964	(9,946)
Inventories	(15,311)	(12,116)
Prepaid expenses and other assets	70	570
Accounts payable	684	(2,509)
Accrued payroll and related benefits	(9,153)	(1,538)
Accrued expenses and other current liabilities	8,366	1,508
Accrued warranty liability	(260)	160
Deferred revenue	1,305	1,117
Operating lease liabilities	(548)	(360)
Net cash used in operating activities	(76,910)	(69,457)
Cash flows from investing activities:		
Purchases of property and equipment	(3,475)	(1,766)
Purchases of investment securities	(133,015)	(122,401)
Sales and maturities of investment securities	101,784	19,900
Net cash used in investing activities	(34,706)	(104,267)
Cash flows from financing activities:		
Proceeds from stock option exercises and employee stock purchase plan purchases	4,765	3,941
Proceeds from issuance of common stock upon follow-on public offerings, net of issuance costs	—	149,085
Net cash provided by financing activities	4,765	153,026
Net decrease in cash, cash equivalents and restricted cash	(106,851)	(20,698)
Cash, cash equivalents and restricted cash as of beginning of period	215,659	328,283
Cash, cash equivalents and restricted cash as of end of period	$ 108,808	$ 307,585
Supplemental cash flow disclosures:		
Cash paid for income taxes	$ 283	$ 42
Cash paid for interest	$ 621	$ 149
Cash paid for amounts included in the measurement of operating lease liabilities	$ 548	$ 360
Supplemental non-cash investing and financing activities:		
Capital expenditures included in accounts payable and accrued expenses	$ 1,613	$ 92
Transfer of inventories to property and equipment	$ —	$ 1,294

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, CA.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. During the six months ended June 30, 2022 and 2021, the Company incurred a net loss of $80.7 million and $60.2 million, respectively. As of June 30, 2022, the Company had an accumulated deficit of $706.7 million.

As of June 30, 2022, the Company had cash, cash equivalents and short-term investments of $262.1 million, which are available to fund future operations, and restricted cash of $33.3 million, for a total cash, cash equivalents, restricted cash and short-term investments balance of $295.4 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 and cash generated from sales, 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 six-month periods are also unaudited. The results of operations for the three and six months ended June 30, 2022 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, 2021 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, 2021, which are included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission (SEC) on February 23, 2022 (2021 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

During the six months ended June 30, 2022, there have been no material changes to the Company's significant accounting policies as described in its 2021 Annual Report that have had a material impact on the Company's condensed financial statements and related notes.

Recently Issued Accounting Pronouncements Not Yet Adopted

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. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022 for all entities except SEC reporting companies that are not smaller reporting companies. ASU 2016-13 will be effective for the Company beginning January 1, 2023. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its financial statements.

3. Revenue and Deferred Revenue

Disaggregation of Revenue

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Consoles	$ 13,228	$ 16,857	$ 31,279	$ 31,623
Consumables	6,393	3,771	14,006	7,215
Total product revenue	19,621	20,628	45,285	38,838
Service and other revenue	5,436	4,588	10,322	9,294
Total revenue	$ 25,057	$ 25,216	$ 55,607	$ 48,132

For the three and six months ended June 30, 2022, $0.7 million and $1.4 million of consoles revenue were from console operating lease arrangements, compared to $1.3 million and $2.6 million for the three and six months ended June 30, 2021.

Remaining Performance Obligations and Contract Liabilities

As of June 30, 2022, 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 $8.0 million, which is recorded as deferred revenue on the Company's condensed balance sheets. Of that amount, $7.8 million will be recognized as revenue during the next 12 months and $0.2 million thereafter.

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition. Revenue under these agreements is recognized over the related service period. During the three and six months ended June 30, 2022, the Company recognized $1.7 million and $4.2 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):

		June 30, 2022			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 31,353	$ —	$ —	$ 31,353
Short-term investments:					
U.S. Treasury securities	Level 1	76,950	—	(518)	76,432
Corporate debt	Level 2	78,645	—	(437)	78,208
Commercial paper	Level 2	31,925	—	—	31,925
Total cash equivalents and short-term investments		$ 218,873	$ —	$ (955)	$ 217,918

		December 31, 2021			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 60,844	$ —	$ —	$ 60,844
Short-term investments:					
U.S. Treasury securities	Level 1	18,064	—	(60)	18,004
Corporate debt	Level 2	124,178	2	(125)	124,055
Commercial paper	Level 2	15,081	—	—	15,081
Total cash equivalents and short-term investments		$ 218,167	$ 2	$ (185)	$ 217,984

As of June 30, 2022, the remaining contractual maturities for available-for-sale securities were one month to thirteen months.

Impairment assessments are made at the individual security level at each reporting period. When the fair value of an available-for-sale security is less than its cost at the balance sheet date, a determination is made as to whether the impairment is other-than-temporary and, if it is other-than-temporary, an impairment loss is recognized in earnings equal to the difference between the investment's amortized cost and fair value at such date. As of June 30, 2022, there were three securities with a total fair value of $18.0 million in an unrealized loss position for more than 12 months. The unrealized losses totaling $89,000 as of June 30, 2022 were caused by changes in market interest rates or the widening of market spreads subsequent to the initial purchase of these securities, and not related to the underlying credit of the issuers or the underlying collateral. These securities were issued by public reporting companies with an investment-grade rating by at least one bond credit rating agency. As a result, the Company did not consider these investments to be other-than-temporarily impaired as of June 30, 2022. During the three and six months ended June 30, 2022 and 2021, the Company did not recognize other-than-temporary impairment losses related to its investment securities.

5. Balance Sheet Components

Cash, Cash Equivalents and Restricted Cash

As of June 30, 2022 and December 31, 2021, the restricted cash balance of $33.3 million primarily relates to contractual obligations under the SVB Loan and Security Agreement (see Note 7) and collateral for 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):

	June 30,	
	2022	2021
Cash and cash equivalents	$ 75,497	$ 274,274
Restricted cash	33,311	33,311
Total cash, cash equivalents and restricted cash	$ 108,808	$ 307,585

Inventories

Inventories consist of the following (in thousands):

	June 30, 2022	December 31, 2021
Raw materials	$ 20,731	$ 18,114
Work in process	9,434	6,054
Finished goods	23,524	15,017
Total inventories	$ 53,689	$ 39,185

Accrued Expenses and Other Current Liabilities

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

	June 30, 2022	December 31, 2021
Accrued inventory	$ 9,904	$ 4,808
Accrued research and development expenses	1,113	574
Accrued professional services	1,745	1,269
Accrued rebate	3,737	3,121
Other	6,762	4,017
Total accrued expenses and other current liabilities	$ 23,261	$ 13,789

6. Commitments and Contingencies

Litigation

On July 8, 2022, a purported stockholder class action lawsuit was filed in the U.S. District Court for the Northern District of California, naming the Company, its Chief Executive Officer, Chief Financial Officer, and former Chief Financial Officer as defendants. The complaint alleges that between September 15, 2020 and June 13, 2022, the defendants violated Sections 10(b) and 20(a) of the Securities Exchange Act of 1934, as amended (Exchange Act) by making false or misleading statements regarding the Company's regulatory studies of the Tablo Hemodialysis System for at home use and the Company's prospects related to the sale of the system for at home use. The Company intends to vigorously defend against this litigation. The case is at a very early stage and there can be no assurance that the Company will be successful in its defense. For this same reason, the Company cannot currently estimate the loss or the range of possible losses it may experience in connection with this litigation.

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

Indemnification

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

7. Term Loan

Term loan consists of the following (in thousands):

	June 30, 2022	December 31, 2021
Principal of term loan	$ 30,000	$ 30,000
Unamortized debt discount	(194)	(238)
Term loan, current and noncurrent	29,806	29,762
Less: term loan, current	(1,000)	—
Total term loan, noncurrent	$ 28,806	$ 29,762

SVB Loan and Security Agreement

On July 2, 2020, the Company entered into a senior secured term loan facility with Silicon Valley Bank (SVB) (the SVB Loan and Security Agreement), which provides for a $30.0 million term loan (the SVB Term Loan).

The SVB Term Loan matures on November 1, 2025. Payments under the SVB Term Loan are for interest only through May 2023, and then 30 monthly principal and interest payments from June 2023 until maturity. The SVB Term Loan bears interest at the greater of (A) 0.5% above the Prime Rate as reported in the Wall Street Journal and (B) 3.75% (5.25% as of June 30, 2022). The Company is obligated to maintain a restricted cash balance greater or equal to the outstanding principal balance of $30.0 million of the SVB Term Loan.

8. Equity Incentive Plan

Equity Incentive Plans

On January 1, 2022, the number of shares of common stock reserved for the issuance of awards under the Company's 2020 Equity Incentive Plan (the 2020 Plan) was increased by 1,890,000 shares as a result of the automatic increase pursuant to the 2020 Plan. As of June 30, 2022, 5,022,000 shares were reserved for future issuance under the 2020 Plan.

Employees Share Purchase Plan (ESPP)

On January 1, 2022, the number of shares of common stock reserved for purchase under the Company's ESPP was increased by 472,000 shares as a result of the automatic increase pursuant to the ESPP. As of June 30, 2022, 1,416,000 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 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 Relative TSR PSUs).

The 2023 target for the Home PSUs is expected to be determined and approved by the Compensation Committee in late 2022 or early 2023. Given such target has not yet been established, the grant date for these 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 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Cost of revenue	$ 190	$ 62	$ 283	$ 137
Research and development	1,808	643	2,966	1,808
Sales and marketing	2,864	1,052	4,570	2,794
General and administrative	2,552	2,180	4,601	5,050
Total stock-based compensation expense	$ 7,414	$ 3,937	$ 12,420	$ 9,789

9. Income Taxes

For each of the three and six months ended June 30, 2022 and 2021, the Company incurred an income tax provision of an insignificant amount, which related to foreign income taxes. 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 June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Stock options to purchase common stock	2,900	4,653	2,900	4,653
Restricted stock units	1,513	473	1,513	473
Performance stock units	31	—	31	—
Shares committed under ESPP	101	27	101	27
Warrant to purchase common stock	63	63	63	63
Total	4,608	5,216	4,608	5,216

11. Subsequent Event

On July 8, 2022, a purported stockholder class action lawsuit was filed against the Company, certain of its officers and a former officer (see Note 6).

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

The following discussion of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes and other financial information included elsewhere in this Quarterly Report, as well as our audited financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our 2021 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 new 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 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 we have conducted, patients have reported experiencing fewer symptoms and better quality sleep while on Tablo. We believe Tablo empowers patients, who have traditionally been passive recipients of care, to regain agency and ownership of their treatment.

Tablo is cleared by the FDA for use in the hospital, clinic, or home setting. 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. During the hold, we continued to market and ship Tablo for use by healthcare professionals in chronic and acute care settings. In addition, the devices that were already distributed to home users at the time the hold was implemented were not removed and current users were able to continue working

with their healthcare providers on appropriate treatment. In late July 2022, the FDA cleared our 510(k) application of Tablo for patient use in the home and we have resumed marketing and shipping Tablo for home use.

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 well suited for home-based dialysis. 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 rapid 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.

We sell our solutions through our direct sales organization, which covers most major metropolitan markets in the United States. As of June 30, 2022, our sales organization was comprised of 36 capital sales team members, responsible for generating new customer demand for Tablo, and 97 clinical sales team members, responsible for driving utilization and fleet expansion of Tablo consoles at existing customer sites. In addition, our field service team, comprised of 117 members, provides maintenance services and product support to Tablo customers. The same sales organization and field service team have driven Tablo penetration in both the acute and home care 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 per-treatment consumables, including the Tablo cartridge, which generates significant total revenue over the life of the console. We generate additional recurring revenue via annual service contracts and revenue from shipping and handling charged to customers. Our total revenue was $25.1 million and $25.2 million for the three months ended June 30, 2022 and 2021, respectively, and $55.6 million and $48.1 million for the six months ended June 30, 2022 and 2021, 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 June 30, 2022 and 2021, we incurred net losses of $43.8 million and $30.2 million, respectively, and for the six months ended June 30, 2022 and 2021, we incurred net losses of $80.7 million and $60.2 million, respectively. As of June 30, 2022, we had an accumulated deficit of $706.7 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 in part on 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 recover from the interruption to, and loss of momentum in, our home commercialization and marketing as we re-engage with our home provider customers, rebuild our patient pipeline and resume supporting new patients in the home following the release of our prior home shipment hold, as well as 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, in the first quarter of 2021, we successfully began production at our own console manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. Second, following our receipt of 510(k) clearance from the FDA for the new cartridge sterilization method in the fourth quarter of 2021, we have qualified a second source to increase Tablo cartridge production through a new manufacturing partner in Mexico, which we anticipate will result in cost reductions from lower freight costs. Third, we will continue to drive scale across our console platform to leverage our supply base and help improve our manufacturing efficiency. 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 these and other measures to control the costs of our products being successful. Likewise, it will be important that we effectively manage the costs of generating our service revenue.

Impacts of the COVID-19 Pandemic and Other Macroeconomic Factors

Our business may be impacted by an escalation or a continuation of the ongoing COVID-19 pandemic. While the operations at our contract manufacturing partners' facilities and our outsourced business administration service provider, TACNA, for our facility in Tijuana, Mexico, have not yet experienced significant disruption as a result of the pandemic, the possibility that such disruption may occur remains. Additionally, the COVID-19 pandemic has at various times since its onset disrupted the operations of certain of our third-party suppliers, resulting in increased lead-times, higher component costs, and lower allocations for our purchase of some components (including certain critical components) and, in certain cases, requiring us to procure materials from alternative sources, procure higher quantities of materials when they become available, or incur higher logistical expenses. 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.

Additionally, surges and shifts in consumer demand as the economy reopens, further exacerbated by COVID-19 outbreaks and protocols, have strained the global freight network and placed significant stress on air, ocean, and ground freight carriers. This has resulted in labor shortages, container and chassis shortages, reduced carrier capacity, carrier delays and longer lead times, shipment receiving and unloading backlogs at many U.S. ports, and escalating freight costs. During the fourth quarter of 2021, these supply chain disruptions escalated, and we are facing increased supply chain constraints, notably with the transportation of Tablo cartridges from our contract manufacturing partner in Southeast Asia. As a result, we have faced, and may continue to face, increased transportation and related costs associated with delivering adequate supply of Tablo treatments to our customers. In the fourth quarter of 2021, we qualified a second source to increase Tablo cartridge production through a new manufacturing partner in Mexico. While we anticipate that this second source will help mitigate supply chain challenges and reduce the need for costly and capacity-constrained air freight delivery of the cartridges, there is no assurance that we will not continue to face supply chain constraints. Continued escalation of these supply chain disruptions and a sustained rise in freight costs 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.

The extent, duration and full impacts of the pandemic remain uncertain and depend on ongoing developments, including but not limited to any resurgences of the virus including emerging variant strains, actions taken to contain or mitigate its impact, as well as the direct and indirect economic effects of the pandemic and related containment measures. Additionally, the duration and severity of disruptions in the global supply chain also remains uncertain, and depend on various factors, including the effectiveness of government actions intended to mitigate these disruptions. As a result, we cannot predict what effect the pandemic, the associated containment measures, and the current supply chain disruptions will ultimately have on our business and results of operations, on our customers, or on our suppliers and vendors. There is no assurance that we will not experience more significant disruptions in our supply chain in the future, particularly if the operations of our contract manufacturing partners, our critical single-source component providers, or the facility we operate in Tijuana, Mexico in collaboration with TACNA, are more severely impacted by the pandemic and associated containment measures.

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 have been exacerbated by the 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. These challenging labor market conditions in the healthcare industry have been heightened by the increased demand for, and demand upon, nurses and other staff resulting from the pandemic. 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 also 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 the second quarter of 2022, our existing and potential customers began to face 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. Toward the end of the quarter, we began to see early indications of the impact these factors had across 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 the second quarter of 2022. If our customers continue to face prolonged staffing shortages, volatility, uncertainty, rising costs and financial pressures, whether due to the pandemic, general macroeconomic conditions or otherwise, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, and have a material adverse effect on our bookings, revenues, results of operations, and, ultimately, our future growth and profitability.

Results of Operations

The following table summarizes our results of operations for the three and six months ended June 30, 2022 and 2021 (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2022	2021	2022	2021
Revenue:				
Product revenue	$ 19,621	$ 20,628	$ 45,285	$ 38,838
Service and other revenue	5,436	4,588	10,322	9,294
Total revenue	25,057	25,216	55,607	48,132
Cost of revenue:				
Cost of product revenue	17,718	22,077	40,828	42,654
Cost of service and other revenue	3,557	2,087	6,555	4,137
Total cost of revenue	21,275	24,164	47,383	46,791
Gross profit	3,782	1,052	8,224	1,341
Operating expenses:				
Research and development	13,521	8,032	24,352	15,602
Sales and marketing	23,198	13,204	43,575	26,353
General and administrative	10,784	9,722	20,493	18,968
Total operating expenses	47,503	30,958	88,420	60,923
Loss from operations	(43,721)	(29,906)	(80,196)	(59,582)
Interest income and other income, net	459	164	579	276
Interest expense	(481)	(431)	(903)	(853)
Loss before provision for income taxes	(43,743)	(30,173)	(80,520)	(60,159)
Provision for income taxes	96	35	211	74
Net loss	$ (43,839)	$ (30,208)	$ (80,731)	$ (60,233)

Comparison of the Three and Six Months Ended June 30, 2022 and 2021

Revenue

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
(dollars in thousands)	2022	2021	$	%	2022	2021	$	%
Revenue:								
Product revenue	$ 19,621	$ 20,628	$ (1,007)	(5)%	$ 45,285	$ 38,838	$ 6,447	17%
Service and other revenue	5,436	4,588	848	18%	10,322	9,294	1,028	11%
Total revenue	$ 25,057	$ 25,216	(159)	(1)%	$ 55,607	$ 48,132	7,475	16%

Product revenue decreased by $1.0 million, or 5% for the three months ended June 30, 2022 as compared to the same quarter in the prior year. This decrease was driven by a $3.6 million decrease in consoles revenue primarily due to the lengthening of sales and installation cycles in the acute care market as a result of staffing challenges and, potentially, other macroeconomic factors highlighted above, impacting our customers, as well as disruption from the home shipment hold due in part to customer uncertainty around the hold, and a $0.6 million decrease in console leasing revenue. This decrease was partially offset by a $2.6 million increase in consumables revenue driven by the growth in our console installed base.

Product revenue increased by $6.4 million, or 17% for the six months ended June 30, 2022 as compared to the same period in the prior year, driven by a $6.8 million increase in consumables revenue attributable to the growth in our console installed base and higher average selling price for consumables. This increase was partially offset by a net $0.3 million decrease in consoles revenue which, in turn, was comprised of a $1.2 million decrease in console leasing revenue, offset by a $0.9 million increase resulting from a higher volume of consoles sold at higher average selling price.

Service and other revenue increased for the three and six months ended June 30, 2022 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 offset by a decrease in service revenue from leased consoles.

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 this 510(k) application of Tablo for patient use in the home and we have resumed marketing and shipping Tablo for home use. The shipment hold on Tablo for home use had a significant negative impact on our bookings and revenue for the second quarter of 2022, as well as on our pipeline of potential new deals. While we have resumed

marketing and shipping Tablo for home use, we may continue to experience disruptions to our home and acute business and operations that could materially and adversely impact our revenue as we recover from the interruption to, and loss of momentum in, our home commercialization and marketing, as well as related disruptions to our acute business due in part to customer uncertainty around the hold. In addition, we anticipate that our revenues may continue to be negatively impacted by the staffing challenges and, potentially, other macroeconomic factors highlighted above, affecting our customers. While we plan to take steps to further evolve our commercial infrastructure and sales processes to support our future growth in both the home and acute markets, we expect these factors may continue to moderate our revenue growth over the next several quarters.

Gross Profit and Gross Margin

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
(dollars in thousands)	2022	2021	$	%	2022	2021	$	%
Gross profit	3,782	1,052	2,730	260%	8,224	1,341	6,883	513%
Gross margin	*15.1* %	*4.2* %			*14.8* %	*2.8* %		

Gross profit increased by $2.7 million, or 260% for the three months ended June 30, 2022 as compared to the same quarter in the prior year. The gross margin percentage improved by 10.9 percentage points for the three months ended June 30, 2022, as compared to the same quarter in the prior year. This improvement in gross profit and gross margin was primarily driven by the impact of our cost reduction activities and the product revenue mix. Such improvement was partially offset by the lower gross margin of service and other revenue due to the planned expiration of a component of a customer lease agreement.

Gross profit increased by $6.9 million, or 513% for the six months ended June 30, 2022 as compared to the same period in the prior year. The gross margin percentage improved by 12.0 percentage points for the six months ended June 30, 2022, as compared to the same period in the prior year. This improvement in gross profit and gross margin was primarily driven by the impact of our cost reduction activities and the product revenue mix and. Such improvement was partially offset by the lower gross margin of service and other revenue due to the planned expiration of a component of a customer lease agreement.

Operating Expenses

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
(dollars in thousands)	2022	2021	$	%	2022	2021	$	%
Operating expenses:								
Research and development	$ 13,521	$ 8,032	$ 5,489	68%	$ 24,352	$ 15,602	$ 8,750	56%
Sales and marketing	23,198	13,204	9,994	76%	43,575	26,353	17,222	65%
General and administrative	10,784	9,722	1,062	11%	20,493	18,968	1,525	8%
Total operating expenses	$ 47,503	$ 30,958	16,545	53%	$ 88,420	$ 60,923	27,497	45%

Research and development expenses increased by $5.5 million, or 68% for the three months ended June 30, 2022, and by $8.8 million or 56% for the six months ended June 30, 2022, in each case, as compared to the same periods in the prior year. These increases were primarily due to higher headcount and higher consulting services to support our product development activities. In addition, there were increased infrastructure costs to support our growth.

Sales and marketing expenses increased by $10.0 million, or 76% for the three months ended June 30, 2022 as compared to the same quarter in the prior year. The increase was primarily driven by higher headcount and increased infrastructure costs to support our growth. In addition, there were higher travel and freight expenses for the three months ended June 30, 2022, as compared with the same quarter in the prior year. This increase was slightly offset by lower consulting expenses.

Sales and marketing expenses increased by $17.2 million or 65% for the six months ended June 30, 2022 as compared to the same period in the prior year. The increase was primarily driven by higher headcount, higher commissions due to higher sales, and increased infrastructure costs to support our growth. In addition, there were higher travel and freight expenses for the six months ended June 30, 2022, as compared with the same quarter in the prior year. This increase was partially offset by lower consulting expenses.

General and administrative expenses increased by $1.1 million or 11% for the three months ended June 30, 2022 as compared to the same quarter in the prior year. The increase was primarily driven by higher headcount and higher travel expenses to support our growth. The increase was partially offset by a decrease in outside services costs.

General and administrative expenses increased by $1.5 million or 8% for the six months ended June 30, 2022 as compared to the same period in the prior year. The increase was primarily driven by higher headcount and increased infrastructure costs to support our growth. In addition, there were higher travel and insurance expenses for the six months ended June 30, 2022 as compared with the same quarter in the prior year. The increase was partially offset by a decrease in outside services costs and a decrease in stock-based

compensation expense due to the expense related to stock options with performance and market-based vesting conditions in 2020, which was fully recognized as of the end of the third quarter of 2021.

Other Income (Expense), Net

	Three Months Ended June 30,		Change		Six Months Ended June 30,		Change	
(dollars in thousands)	2022	2021	$	%	2022	2021	$	%
Other income (expenses), net:								
Interest income and other income, net	$ 459	$ 164	$ 295	180 %	$ 579	$ 276	$ 303	110 %
Interest expense	(481)	(431)	(50)	12 %	(903)	(853)	(50)	6 %
Total other expenses, net	$ (22)	$ (267)	245	(92)%	$ (324)	$ (577)	253	(44)%

The increase in interest income and other income, net for the three and six months ended June 30, 2022 as compared to the same periods in the prior year was driven by higher interest rates.

Interest expense for the three and six months ended June 30, 2022 were relatively consistent with the amounts for the same periods in the prior year.

Liquidity and Capital Resources

Sources of Liquidity

As of June 30, 2022, we had cash, cash equivalents and short-term investments of $262.1 million, which are available to fund future operations, and restricted cash of $33.3 million, for a total cash, cash equivalents, restricted cash and short-term investments balance of $295.4 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 financings, and proceeds from stock option exercises and employee stock purchases.

We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term while we make investments to support our anticipated growth. We may raise additional capital through the issuance of additional equity financing, debt financings, including through refinancing our existing debt, or other sources. If this financing is not available to us at adequate levels or on acceptable terms, we may need to reevaluate our operating plans. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be 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, and cash generated from sales of our products and services, 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):

	Six Months Ended June 30,	
	2022	2021
Net cash (used in) provided by:		
Operating activities	$ (76,910)	$ (69,457)
Investing activities	(34,706)	(104,267)
Financing activities	4,765	153,026
Net decrease in cash, cash equivalents and restricted cash	$ (106,851)	$ (20,698)

Operating Activities

The net cash used in operating activities of $76.9 million for the six months ended June 30, 2022 was due to a net loss of $80.7 million and a net cash outflow from the change in our operating assets and liabilities of $13.9 million, which were partially offset by adjustments for stock-based compensation expense of $12.4 million, depreciation and amortization of $2.6 million, accretion of discount on investments of $1.0 million, provision for inventories of $0.8 million, non-cash lease expense of $0.5 million, and non-cash interest expense of $0.3 million. The net cash outflow from operating assets and liabilities was primarily driven by an increase in inventories as a result of the timing of inventory purchases including advance purchases of inventory due to anticipated demand and to mitigate supply chain disruptions, a decrease in accrued payroll and related benefits, a decrease in operating lease liabilities and accrued warranty liability. The net cash outflow from operating assets and liabilities was partially offset by an increase in accounts payable and accrued expenses and other current liabilities due to timing of vendor payments, an increase in deferred revenue as a result of the growth of our business, a decrease in accounts receivable resulting from the timing of collections, and a decrease in prepaid expenses and other assets.

The net cash used in operating activities of $69.5 million for the six months ended June 30, 2021 was due to a net loss of $60.2 million and a net cash outflow from the change in our operating assets and liabilities of $23.1 million, which were partially offset by adjustments for stock-based compensation expense of $9.8 million, depreciation and amortization of $2.6 million, non-cash lease expense of $0.5 million, accretion of discount on investments of $0.4 million, non-cash interest expense of $0.3 million, and provision for inventories of $0.3 million. The net cash outflow from operating assets and liabilities was primarily driven by an increase in inventories as a result of the timing of inventory purchases including advance purchases of inventory for the transition to our own manufacturing facility, anticipated demand and to mitigate supply chain disruptions, which partially related to COVID-19, an increase in accounts receivable due to timing of collections, a net decrease in account payable, accrued expenses and other current liabilities resulting from the timing of vendor payments and a decrease in accrued payroll and related benefits, and a decrease in operating lease liabilities. The net cash outflow from operating assets and liabilities was partially offset by an increase in deferred revenue as a result of the growth of our business, an increase in prepaid expenses and other assets, and an increase in accrued warranty liability.

Investing Activities

The net cash used in investing activities of $34.7 million for the six months ended June 30, 2022 was due primarily to the purchases of investment securities of $133.0 million and the purchases of property and equipment of $3.5 million, partially offset by the sales and maturities of investment securities of $101.8 million.

The net cash used in investing activities of $104.3 million for the six months ended June 30, 2021 was due primarily to the purchases of investment securities of $122.4 million and the purchases of property and equipment of $1.8 million, partially offset by the sales and maturities of investment securities of $19.9 million.

Financing Activities

The net cash provided by financing activities of $4.8 million for the six months ended June 30, 2022 was due to proceeds of $4.8 million from employee exercises of stock options and ESPP purchases.

The net cash provided by financing activities of $153.0 million for the six months ended June 30, 2021 was due primarily to the net proceeds of $149.1 million from the issuance of our common stock upon the follow-on offering and the proceeds of $3.9 million from employee exercises of stock options and ESPP purchases.

Contractual Obligations and Commitments

During the six months ended June 30, 2022, there have been no material changes to our contractual obligations from those disclosed in "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" included in our 2021 Annual Report.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

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 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 2021 Annual Report. For additional information, please refer to Note 2 to our unaudited condensed financial statements in this Quarterly Report.

Recent Accounting Pronouncements

See Note 2 to our unaudited condensed financial statements included elsewhere in this Quarterly Report for more information.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no material change in the nature of the Company's interest rate risks or foreign currency exchange risks from those described in Part II Item 7A of our 2021 Annual Report.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

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

Item 1A. Risk Factors.

You should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 2021 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 Mach 31, 2022 ("Q1 2022 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 2021 Annual Report, as updated by our Q1 2022 Quarterly Report, except as set forth below. The risks described in our 2021 Annual Report and our Q1 2022 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.

While we recently resumed marketing and shipping the Tablo System for home use following the FDA's clearance of our most recent 510(k) submission, our business and operations may continue to experience disruptions as a result of the prior shipment hold. In addition, as we continue to modify Tablo from time to time, such modifications may require new 510(k) clearances from the FDA, which we may not be able to obtain on a timely basis or at all.

Since Tablo's original clearance by the FDA for home use in March 2020, we have made certain changes to the device over time. In May 2021, we submitted a "catch-up" 510(k) application to the FDA covering the design changes for patient use in the home. In May 2022, after further discussions with the FDA and receiving indications that the clearance of this 510(k) application would be delayed beyond our original expectations, 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 this 510(k) application. In late July 2022, the FDA cleared this 510(k) application of Tablo for patient use in the home and we have resumed marketing and shipping Tablo for home use.

The shipment hold on Tablo for home use had a significant negative impact on our bookings and revenue for the second quarter of 2022, as well as on our pipeline of potential new deals. Following the most recent 510(k) clearance, we have resumed marketing and shipping Tablo for home use. However, we may continue to experience disruptions to our home and acute business and operations that could materially and adversely impact our results of operations, financial condition and growth prospects as we recover from the interruption to, and loss of momentum in, our home commercialization and marketing, related disruptions to our acute business, and any negative effects to our reputation as a result of the hold.

Moreover, as we continue to modify Tablo from time to time, we may determine that such modifications could significantly affect safety and effectiveness of the device and thereby require new 510(k) clearances. Further, even in instances where we determine modifications to Tablo do not require a new 510(k) clearance, the FDA may disagree and we may ultimately be required to make additional changes to the Tablo System, we may need to submit a new 510(k) application and obtain clearance, we may be required to temporarily suspend shipment of, withdraw or recall Tablo until such 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, all of which would materially and adversely disrupt and harm our business and future growth. Where we determine that modifications to Tablo do require a new 510(k) clearance from the FDA, we may not be able to obtain such clearance in a timely manner, or at all. Obtaining clearances can be a time-consuming process, and delays in obtaining required future clearances could adversely affect our ability to make updates to Tablo in a timely manner, which in turn would harm our future growth.

Our customers are facing staffing shortages, increased costs and other financial pressures 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 have been exacerbated by the 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. These challenging labor market conditions in the healthcare industry have been heightened by the increased demand for, and demand upon, nurses and other staff resulting from the pandemic. 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 the second quarter of 2022, our existing and potential customers began to face 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. Toward the end of the quarter, we began to see early indications of the impact these factors had across 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 the second quarter of 2022. If our customers continue to face prolonged volatility, uncertainty, staffing shortages, rising costs and financial pressures, whether due to the pandemic, general macroeconomic conditions or otherwise, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, and have a material adverse effect on our bookings, revenues, results of operations, and, ultimately, our future growth and profitability.

We may in the future become subject to a post-market surveillance order issued by the FDA for our Tablo System that could lead to making changes to or recalling or withdrawing the Tablo System from the field, or modifications to our labeling, which could harm our business.

The FDA has previously notified us that the Tablo System is subject to a mandatory post-market surveillance order under Section 522 of the Federal Food Drug and Cosmetic Act (FDCA), requiring that we conduct a human factors study encompassing both summative and real-world data, as well as conduct a detailed analysis of adverse events and complaints from home users. Because the version of the Tablo System and software that was subject to the 510(k) application for home use submitted in May 2021 was the version we planned to use in the human factors study, we had intended to initiate the human factors study in accordance with our approved 522 study protocol upon FDA clearance of that 510(k) application. In July 2022, the FDA notified us that they have placed the 522 study requirement on hold because the original order specifically pertained to a prior version of Tablo. It currently remains uncertain whether the FDA will issue a new 522 order applicable to the current version of Tablo or extend the requirements of the prior 522 study order to apply to the version of Tablo that is the subject of the recently cleared 510(k). If the FDA does require us to run a 522 study with the version of Tablo that is the subject of the most recent clearance, we would need to submit and obtain the FDA's approval of an updated 522 study protocol for the current version of Tablo before we could commence, conduct and complete the study. Should the FDA decide that the use of the Tablo System in the home environment identifies new concerns related to the safety and effectiveness of the product, or if the FDA determines that the requirements of the 522 order are otherwise unmet, we may be required to make changes to our Tablo System or its labeling for which we may need to submit new marketing authorization applications and obtain clearance, we may need to temporarily suspend shipment of Tablo, withdraw or recall the Tablo System from the market, and we may be subject to other enforcement actions, any of which could materially and adversely harm our business.

Litigation and other legal proceedings may adversely affect our business.

From time to time we may become involved in legal proceedings relating to patent and other intellectual property matters, product liability claims, employee claims, tort or contract claims, federal regulatory investigations, securities class action and other legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. For example, on July 8, 2022, a purported stockholder class action lawsuit was filed against the Company, our Chief Executive Officer, Chief Financial Officer and former Chief Financial Officer, in the U.S. District Court for the Northern District of California alleging that the defendants violated federal securities laws by making false or misleading statements regarding the Company's regulatory studies of the Tablo Hemodialysis System for at home use and the Company's prospects related to the sale of the system for at home use. For further information, see the section entitled "Litigation" in Note 6, Commitments and Contingencies, to our unaudited condensed financial statements included in this Quarterly Report. Litigation is inherently unpredictable and can result in excessive or unanticipated verdicts and/or injunctive relief that affect how we operate our business. We could incur judgments or enter into settlements of claims for monetary damages or for agreements to change the way we operate our business, or both. There may be an increase in the scope of these matters or there may be additional lawsuits, claims, proceedings or investigations in the future, which could have a material adverse effect on our business, financial condition and results of operations. Adverse publicity about regulatory or legal action against us could damage our reputation and brand image, undermine our customers' confidence and reduce long-term demand for Tablo, even if the regulatory or legal action is unfounded or not material to our operations.

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

(a) Sales of Unregistered Securities

Not applicable.

(b) Use of Proceeds from Public Offering of Common Stock

The offer and sale of shares in our IPO was registered under the Securities Act pursuant to a registration statement on Form S-1 (File No.333-248225), which was declared effective by the SEC on September 17, 2020. The remainder of the information required by this item regarding the use of our IPO proceeds has been omitted pursuant to SEC rules because such information has not changed since our last periodic report was filed.

(c) Repurchases

Not applicable.

Item 3. Defaults Upon Senior Securities.

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None.

Item 6. Exhibits.

Exhibit Number	Description	Incorporation by Reference			
		Form	File No.	Exhibit	Filing Date
3.1	Form of Amended and Restated Certificate of Incorporation of Outset Medical, Inc.	S-1/A	333-248225	3.1	September 9, 2020
3.2	Form of Amended and Restated Bylaws of Outset Medical, Inc.	S-1/A	333-248225	3.2	September 9, 2020
4.1	Form of Common Stock Certificate	S-1/A	333-248225	4.1	September 9, 2020
4.2	Amended and Restated Registration Rights Agreement	S-1	333-248225	4.2	August 21, 2020
4.3	Form of Series A Warrant Agreement #1	S-1	333-248225	4.3	August 21, 2020
4.4	Form of Series A Warrant Agreement #2	S-1	333-248225	4.4	August 21, 2020
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: August 2, 2022 By: /s/ Leslie Trigg
Leslie Trigg
President and Chief Executive Officer
(*Principal Executive Officer*)

Date: August 2, 2022 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: August 2, 2022

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: August 2, 2022

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 June 30, 2022, 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.

August 2, 2022 By: /s/ Leslie Trigg
Leslie Trigg
Chief Executive Officer
(*Principal Executive Officer*)

August 2, 2022 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.