UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2021

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 ☒

Indicate by check mark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes ☒ No ☐

As of October 29, 2021, the registrant had 47,094,315 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)

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 230,508	$ 294,972
Short-term investments	142,535	19,898
Accounts receivable, net	19,302	6,468
Inventories	34,297	18,384
Prepaid expenses and other current assets	6,659	6,189
Total current assets	433,301	345,911
Restricted cash	33,311	33,311
Property and equipment, net	14,532	14,998
Operating lease right-of-use assets	7,494	8,253
Other assets	166	1,356
Total assets	$ 488,804	$ 403,829
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,702	$ 4,948
Accrued compensation and related benefits	17,759	16,845
Accrued expenses and other current liabilities	11,389	7,903
Accrued warranty liability	3,234	2,913
Deferred revenue, current	5,212	3,201
Operating lease liabilities, current	1,109	882
Total current liabilities	41,405	36,692
Accrued interest, noncurrent	600	240
Deferred revenue, noncurrent	109	570
Operating lease liabilities, noncurrent	7,199	8,044
Term loan, noncurrent	29,740	29,674
Total liabilities	79,053	75,220
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of September 30, 2021 and December 31, 2020	—	—
Common stock, $0.001 par value; 300,000 shares authorized as of September 30, 2021 and December 31, 2020; 47,018 and 42,722 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	47	43
Additional paid-in capital	994,486	822,624
Accumulated other comprehensive (loss) income	(20)	1
Accumulated deficit	(584,762)	(494,059)
Total stockholders' equity	409,751	328,609
Total liabilities and stockholders' equity	$ 488,804	$ 403,829

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Revenue:				
Product revenue	$ 21,824	$ 10,812	$ 60,662	$ 26,435
Service and other revenue	4,494	2,944	13,788	6,253
Total revenue	26,318	13,756	74,450	32,688
Cost of revenue:				
Cost of product revenue	20,526	17,265	63,180	42,118
Cost of service and other revenue	2,846	1,617	6,983	4,024
Total cost of revenue	23,372	18,882	70,163	46,142
Gross profit	2,946	(5,126)	4,287	(13,454)
Operating expenses:				
Research and development	9,729	9,175	25,331	21,066
Sales and marketing	15,726	13,344	42,079	29,870
General and administrative	7,629	13,088	26,597	21,462
Total operating expenses	33,084	35,607	94,007	72,398
Loss from operations	(30,138)	(40,733)	(89,720)	(85,852)
Interest income and other income (expense), net	99	(3)	375	524
Interest expense	(431)	(428)	(1,284)	(2,461)
Change in fair value of redeemable convertible preferred stock warrant liability	—	437	—	(93)
Loss on extinguishment of term loan	—	(1,567)	—	(1,567)
Loss before provision for income taxes	(30,470)	(42,294)	(90,629)	(89,449)
Provision for income taxes	—	—	74	—
Net loss	$ (30,470)	$ (42,294)	$ (90,703)	$ (89,449)
Net loss attributable to common stockholders, basic and diluted	$ (30,470)	$ (42,294)	$ (90,703)	$ (47,281)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.65)	$ (3.44)	$ (1.96)	$ (6.30)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	46,588	12,299	46,252	7,508

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Net loss	$ (30,470)	$ (42,294)	$ (90,703)	$ (89,449)
Other comprehensive income (loss):				
Unrealized gain (loss) on available-for-sale securities	8	1	(21)	(21)
Comprehensive loss	$ (30,462)	$ (42,293)	$ (90,724)	$ (89,470)

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

Outset Medical, Inc.

Condensed Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(Unaudited)

(in thousands)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive Income (Loss)	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital		Deficit	(Deficit)
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
Issuance of common stock through employee stock purchase plan	—	—	36	—	1,596	—	—	1,596
Issuance of common stock for settlement of RSUs	—	—	1	—	—	—	—	—
Stock option exercises	—	—	756	1	4,590	—	—	4,591
Stock-based compensation expense	—	—	—	—	2,864	—	—	2,864
Unrealized income on available-for-sale securities	—	—	—	—	—	8		8
Net loss	—	—	—	—	—	—	(30,470)	(30,470)
Balance as of September 30, 2021	—	$ —	47,018	$ 47	$ 994,486	$ (20)	$ (584,762)	$ 409,751

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

Outset Medical, Inc.

Condensed Statement of Redeemable Convertible Preferred Stock and Stockholders' Equity (Deficit)

(Unaudited)

(in thousands)

	Redeemable Convertible Preferred Stock		Common Stock		Additional Paid-in	Accumulated Other Comprehensive	Accumulated	Total Stockholders' Equity
	Shares	Amount	Shares	Amount	Capital	Income (Loss)	Deficit	(Deficit)
Balance as of December 31, 2019	147,214	$ 409,446	922	$ 1	$ 357	$ 22	$ (372,567)	$ (372,187)
Issuance of Series E redeemable convertible preferred stock, net of issuance costs	57,782	126,758	—	—	—	—	—	—
Issuance of common stock on settlement of accrued dividend	—	(41,763)	4,850	5	41,758	—	—	41,763
Deemed dividend on settlement of accrued dividend	—	(42,530)	—	—	42,530	—	—	42,530
Stock option exercises	—	—	4	—	14	—	—	14
Stock-based compensation expense	—	—	—	—	580	—	—	580
Unrealized loss on available-for-sale securities	—	—	—	—	—	(35)	—	(35)
Adjustment to redemption value on redeemable convertible preferred stock	—	362	—	—	(362)	—	—	(362)
Net loss	—	—	—	—	—	—	(20,650)	(20,650)
Balance as of March 31, 2020	204,996	$ 452,273	5,776	$ 6	$ 84,877	$ (13)	$ (393,217)	$ (308,347)
Stock option exercises	—	—	26	—	80	—	—	80
Stock-based compensation expense	—	—	—	—	683	—	—	683
Unrealized gain on available-for-sale securities	—	—	—	—	—	13	—	13
Net loss	—	—	—	—	—	—	(26,505)	(26,505)
Balance as of June 30, 2020	204,996	$ 452,273	5,802	$ 6	$ 85,640	$ —	$ (419,722)	$ (334,076)
Issuance of common stock upon net exercises of Series B redeemable convertible preferred stock warrants	—	—	65	—	—	—	—	—
Cash exercises of Series C redeemable convertible preferred stock warrants	1,655	4,288	—	—	—	—	—	—
Conversion of Series A redeemable convertible preferred stock warrants to common stock warrants	—	—	—	—	1,252	—	—	1,252
Conversion of redeemable convertible preferred stock to common stock upon initial public offering	(206,651)	(456,561)	26,167	26	456,535	—	—	456,561
Issuance of common stock upon initial public offering, net of issuance costs	—	—	10,294	10	254,795	—	—	254,805
Reclassification of redeemable convertible preferred stock warrant liability to equity	—	—	—	—	3,126	—	—	3,126
Stock option exercises	—	—	373	—	1,050	—	—	1,050
Stock-based compensation expense	—	—	—	—	13,908	—	—	13,908
Unrealized gain on available-for-sale securities	—	—	—	—	—	1	—	1
Net loss	—	—	—	—	—	—	(42,294)	(42,294)
Balance as of September 30, 2020	—	$ —	42,701	$ 42	$ 816,306	$ 1	$ (462,016)	$ 354,333

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

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

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (90,703)	$ (89,449)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	3,866	1,229
Non-cash lease expense	759	351
Non-cash interest expense	426	497
Accretion of discount on investments, net	1,173	60
Provision for accounts receivable	5	29
Provision for inventories	766	443
Loss on disposal of property and equipment	—	5
Stock-based compensation expense	12,653	15,171
Change in fair value of redeemable convertible preferred stock warrant liability	—	93
Loss on extinguishment of term loan	—	1,567
Changes in operating assets and liabilities:		
Accounts receivable	(12,838)	(3,197)
Inventories	(17,925)	(9,236)
Prepaid expenses and other assets	718	(5,397)
Accounts payable	(2,151)	368
Accrued payroll and related benefits	913	3,894
Accrued expenses and other current liabilities	3,496	5,136
Accrued warranty liability	321	1,556
Deferred revenue	1,550	3,681
Accrued interest	—	(217)
Operating lease liabilities	(617)	241
Net cash used in operating activities	(97,588)	(73,175)
Cash flows from investing activities:		
Purchases of property and equipment	(2,257)	(6,446)
Purchases of investment securities	(148,132)	(32,884)
Sales and maturities of investment securities	24,300	32,919
Net cash used in investing activities	(126,089)	(6,411)
Cash flows from financing activities:		
Proceeds from issuance of common stock upon initial and follow-on public offerings, net of issuance costs	149,085	255,728
Proceeds from cash exercise of redeemable convertible preferred stock warrants	—	4,288
Proceeds from issuance of redeemable convertible preferred stock, net of issuance costs	—	126,758
Proceeds from stock option exercises and employee stock purchase plan purchases	10,128	1,144
Proceeds from issuance of term loan, net of issuance costs	—	29,630
Repayment of term loan and extinguishment costs	—	(30,985)
Repayment of finance lease	—	(8)
Net cash provided by financing activities	159,213	386,555
Net (decrease) increase in cash, cash equivalents and restricted cash	(64,464)	306,969
Cash, cash equivalents and restricted cash as of beginning of period	328,283	37,669
Cash, cash equivalents and restricted cash as of end of period	$ 263,819	$ 344,638
Supplemental cash flow disclosures:		
Cash paid for income taxes	$ 72	$ —
Cash paid for interest	$ 858	$ 2,181
Cash paid for amounts included in the measurement of operating lease liabilities	$ 617	$ —

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

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

	Nine Months Ended September 30,	
	2021	**2020**
Supplemental non-cash investing and financing activities:		
Capital expenditures included in accounts payable and accrued expenses	$ 218	$ 601
Transfer of inventories to property and equipment	$ 1,392	$ 1,579
Right-of-use assets obtained in exchange for lease liabilities	$ —	$ 8,849
Deemed dividend on settlement of accrued dividend	$ —	$ 42,530
Adjustment to redemption value on redeemable convertible preferred stock	$ —	$ 362
Conversion of redeemable convertible preferred stock into common stock upon initial public offering	$ —	$ 456,561
Reclassification of redeemable convertible preferred stock warrant liability for conversion of Series A redeemable preferred stock warrants into common stock warrants	$ —	$ 1,252
Reclassification of redeemable convertible preferred stock warrant liability to additional paid-in capital	$ —	$ 3,126
Issuance of common stock on settlement of accrued dividend	$ —	$ 41,763
Initial public offering issuance costs included in accrued expenses	$ —	$ 923

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, U.S. Food and Drug Administration ("FDA") cleared for use from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels, with 2-way wireless data transmission and a proprietary data analytics platform powering a new holistic approach to dialysis care. The Company’s headquarters are located in San Jose, CA.

The Company’s registration statement on Form S-1 related to its initial public offering (“IPO”) was declared effective by the Securities and Exchange Commission (“SEC”) on September 14, 2020, and the Company’s common stock began trading on the Nasdaq Global Select Market on September 15, 2020. Upon the completion of the IPO, the Company sold 10,294,000 shares of common stock (which included 1,343,000 shares that were sold pursuant to the full exercise of the underwriters’ option to purchase additional shares in connection with the IPO) at a price to the public of $27.00 per share. Including the full exercise of the underwriters’ option to purchase additional shares, the Company received aggregate net proceeds of $254.8 million after deducting offering costs, underwriting discounts and commissions of $23.1 million.

On April 13, 2021, the Company completed a follow-on public offering and sold 2,946,000 shares of common stock (which included 446,000 shares that were offered and sold pursuant to the full exercise of the underwriters’ option to purchase additional shares) at a price to the public of $53.50 per share. The Company received aggregate net proceeds of approximately $149.1 million after deducting offering costs, underwriting discounts and commissions of $8.5 million.

Reverse Stock Split

In September 2020, the Company’s board of directors and shareholders approved a certificate of amendment to the amended and restated certificate of incorporation to effect a reverse split of shares of the Company’s common stock on a 7.9-for-one basis (the “Reverse Stock Split”) effective as of September 8, 2020. The number of authorized shares and the par values of the common stock and redeemable convertible preferred stock were not adjusted as a result of the Reverse Stock Split. In connection with the Reverse Stock Split, the conversion ratio for the Company’s outstanding redeemable convertible preferred stock was proportionately adjusted such that the common stock issuable upon conversion of such preferred stock was decreased in proportion to the Reverse Stock Split. All references to common stock and options to purchase common stock share data, per share data and related information contained in these condensed financial statements have been retrospectively adjusted to reflect the effect of the Reverse Stock Split for all periods presented.

Liquidity

Since inception, the Company has incurred net losses and negative cash flows from operations. During the nine months ended September 30, 2021 and 2020, the Company incurred a net loss of $90.7 million and $89.4 million, respectively. As of September 30, 2021, the Company had an accumulated deficit of $584.8 million.

As of September 30, 2021, the Company had cash, cash equivalents and short-term investments of $373.0 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 $406.4 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 and short-term investments, which include the proceeds from the IPO and the follow-on public offering, and cash generated from revenues from its products and services, will be sufficient to meet its anticipated needs for at least the next 12 months from the issuance date of the accompanying condensed financial statements.

Basis of Presentation

The accompanying condensed financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles (“U.S. GAAP”) and on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, that are necessary for the fair statement of the Company’s financial position, results of operations, comprehensive loss and cash flows for the interim periods presented. The financial data and the other financial information disclosed in these notes to the condensed financial statements related to the three-and nine-month period are also unaudited. The results of operations for the three and nine months ended September 30, 2021 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, 2020 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, 2020, which are included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with SEC on March 22, 2021 ("2020 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 three and nine months ended September 30, 2021, there have been no changes to the Company's significant accounting policies as described in its 2020 Annual Report that have had a material impact on the Company's condensed financial statements and related notes, except as described below.

Cash, Cash Equivalents and Restricted Cash

As of September 30, 2021 and December 31, 2020, 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):

	September 30,	
	2021	2020
Cash and cash equivalents	$ 230,508	$ 311,327
Restricted cash	33,311	33,311
Total cash, cash equivalents and restricted cash	$ 263,819	$ 344,638

Stock-Based Compensation Expense

Stock-based compensation expense relates to stock options with a service-based vesting condition, stock options with performance and market-based vesting conditions, stock purchase rights under the Company's Employee Stock Purchase Plan ("ESPP"), restricted stock units ("RSUs") and performance stock units ("PSUs"). Stock-based compensation expense for the Company's stock-based awards is based on their grant date fair value.

Service-based options granted to an optionee generally vest at a rate of 25% on the first anniversary of the original vesting date, with the balance vesting monthly over the remaining three years. The fair value of stock options with a service condition and stock purchase rights under the ESPP on the grant date is estimated using the Black-Scholes option-pricing model. The fair value of these awards is recognized as compensation expense on a straight-line basis over the requisite service period in which the awards are expected to vest and forfeitures are recognized as they occur.

The Black-Scholes model considers several variables and assumptions in estimating the fair value of service-based stock options and stock purchase rights under the ESPP. These variables include the per share fair value of the underlying common stock, exercise price, expected term, risk-free interest rate, expected annual dividend yield and expected stock price volatility over the expected term. For all service-based stock options granted, the Company calculates the expected term using the simplified method for "plain vanilla" stock option awards.

For stock options with performance and market-based vesting conditions, stock-based compensation expense is recognized when it is considered probable that the performance vesting condition will be satisfied. Stock-based compensation expense related to these options is recognized using the accelerated attribution method and not reversed if the achievement of the market condition does not occur. The fair value of these stock options is estimated using the Monte Carlo approach.

RSUs granted to an optionee 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. The fair value of RSUs and PSUs with a service- or performance-based vesting condition is based on the market price of the Company's common stock on the date of grant. The determination of the stock-based compensation expense related to PSUs with a performance-based vesting condition to be recognized requires the use of certain estimates and assumptions. At each reporting period, the Company reassesses the probability of the achievement of corporate performance goals to estimate the number of shares to be released. Any increase or decrease in stock-based compensation expense resulting from an adjustment in the estimated shares to be released is treated as accumulative catch-up in the period of adjustment. If any of the assumptions or estimates used change significantly, stock-based compensation expense may differ materially from what the Company has recorded in the current period. The fair value of PSUs with a market-based vesting condition is estimated using the Monte Carlo approach. Stock-based compensation expense related to these PSUs is recognized using the accelerated attribution method and not reversed if the achievement of the market condition does not occur.

Recently Adopted Accounting Pronouncements

In December 2019, the Financial Accounting Standards Board ("FASB") issued ASU No. 2019-12, *Income Taxes (Topic 740)* ("ASU 2019-12"), which simplifies the accounting for income taxes, primarily by eliminating certain exceptions to ASC 740. The Company early adopted ASU 2019-12 on a modified retrospective basis as of January 1, 2021, which did not have a material impact on the condensed financial statements.

Recently Issued Accounting Pronouncements Not Yet Adopted

In June 2016, the 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 September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Consoles	$ 15,423	$ 9,017	$ 47,046	$ 22,230
Consumables	6,401	1,795	13,616	4,205
Total product revenue	21,824	10,812	60,662	26,435
Service and other revenue	4,494	2,944	13,788	6,253
Total revenue	$ 26,318	$ 13,756	$ 74,450	$ 32,688

For the three and nine months ended September 30, 2021, $1.3 million and $3.9 million of consoles revenue were from console operating lease arrangements, compared to $0.7 million and $1.9 million for the three and nine months ended September 30, 2020.

Performance Obligations and Contract Liabilities

As of September 30, 2021, 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 $5.3 million, which is recorded as deferred revenue on the Company's condensed balance sheets. Of that amount, $5.2 million will be recognized as revenue during the next 12 months and $0.1 million thereafter.

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition related to console service agreements and for prepayments for products or services yet to be delivered. Revenue under these agreements is recognized over the related service period or as products are delivered. Revenue recorded during the three and nine months ended September 30, 2021 included $0.4 million and $3.0 million, respectively, of previously deferred revenue that was included in contract liabilities as of December 31, 2020.

4. Fair Value Measurements

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

		September 30, 2021			
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 75,606	$ —	$ —	$ 75,606
Short-term investments:					
U.S. Treasury securities	Level 1	13,087	1	(4)	13,084
Corporate debt	Level 2	111,673	12	(29)	111,656
Commercial paper	Level 2	15,791	—	—	15,791
Yankee debt securities	Level 2	2,004	—	—	2,004
Total cash equivalents and short-term investments		$ 218,161	$ 13	$ (33)	$ 218,141

		December 31, 2020			
		Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	$ 56,056	$ —	$ —	$ 56,056
Short-term investments:					
U.S. Treasury securities	Level 1	14,999	1	—	15,000
Corporate debt	Level 2	4,898	—	—	4,898
Total cash equivalents and short-term investments		$ 75,953	$ 1	$ —	$ 75,954

As of September 30, 2021, the remaining contractual maturities for available-for-sale securities were between one month to seventeen 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. There were no unrealized losses for securities in an unrealized loss position for more than 12 months as of September 30, 2021. During the three and nine months ended September 30, 2021 and 2020, the Company did not recognize other-than-temporary impairment losses related to its investment securities.

5. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

	September 30, 2021	December 31, 2020
Raw materials	$ 15,465	$ 7,989
Work in process	7,276	6,200
Finished goods	11,556	4,195
Total inventories	$ 34,297	$ 18,384

Accrued Expenses and Other Current Liabilities

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

	September 30, 2021	December 31, 2020
Accrued inventory	$ 3,049	$ 3,576
Accrued research and development expenses	1,034	175
Accrued professional services	1,256	2,187
Accrued rebate	2,420	566
Other	3,630	1,399
Total accrued expenses and other current liabilities	$ 11,389	$ 7,903

Accrued Warranty Liability

The change in accrued warranty liability is presented in the following table (in thousands):

	September 30, 2021	December 31, 2020
Balance at the beginning of the period	$ 2,913	$ 1,702
Additions charged to cost of product revenue	5,250	4,858
Consumption	(4,929)	(3,647)
Balance at the end of the period	$ 3,234	$ 2,913

6. Commitments and Contingencies

Litigation

From time to time, the Company may become involved in legal proceedings or investigations, which could have an adverse impact on its reputation, business and financial condition and divert the attention of the Company’s management from the operation of the Company’s business. The Company is not presently a party to any legal proceedings that, if determined adversely to the Company, would individually or taken together have a material adverse effect on its business, results of operations, financial condition or cash flows.

Indemnification

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

7. Term Loan

Term loan consists of the following (in thousands):

	September 30, 2021	December 31, 2020
Principal of term loan	$ 30,000	$ 30,000
Unamortized debt discount	(260)	(326)
Total term loan, noncurrent	$ 29,740	$ 29,674

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% (3.75% as of September 30, 2021). 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.

There is also a final payment fee equal to 6.75% of the original principal amount of the SVB Term Loan, or approximately $2.0 million, due at maturity (or any earlier date of optional pre-payment or acceleration of principal due to an event of default). Such fee is being accreted to interest expense using the effective interest method with the offset recorded in noncurrent accrued interest. The Company may, at its option, prepay the SVB Term Loan in full, subject to an additional prepayment fee ranging between 1% and 3% of the outstanding principal amount of the SVB Term Loan.

In the event of a default or change in control, all unpaid principal and all accrued and unpaid interest amounts (if any) become immediately due and payable including the prepayment fee. Events of default include, but are not limited to, a payment default, a material adverse change, and insolvency. The SVB Term Loan is secured by substantially all of the Company's assets, including all of the capital stock held by the Company, if any (subject to a 65% limitation on pledges of capital stock of foreign subsidiaries), subject to certain exceptions. The SVB Loan and Security Agreement contains customary representations, warranties, affirmative covenants and also contains certain restrictive covenants.

Debt issuance costs paid directly to SVB and other debt issuance costs amounting to $0.4 million were accounted for as discounts on the SVB Term Loan. These debt discounts, along with the final payment fee, are being amortized over the term of the SVB Term Loan using the effective interest rate method. As of September 30, 2021, the unamortized debt discount was $0.3 million, which is recorded as a direct deduction from the SVB Term Loan on the accompanying condensed balance sheets.

8. Equity Incentive Plan

Equity Incentive Plans

On January 1, 2021, 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 1,709,000 shares as a result of the automatic increase pursuant to the 2020 Plan. As of September 30, 2021, 4,466,000 shares were reserved for future issuance under the 2020 Plan.

Employees Share Purchase Plan (ESPP)

On January 1, 2021, the number of shares of common stock reserved for purchase under the Company's Employee Share Purchase Plan ("ESPP") was increased by 427,000 shares as a result of the automatic increase pursuant to the ESPP. As of September 30, 2021, 999,000 shares of common stock were reserved for issuance in connection with the current and future offering periods under the ESPP.

The price at which common stock is purchased under the ESPP is equal to 85% of the fair market value of the common stock on the first day of the offering period or the purchase date, whichever is lower. During the three and nine months ended September 30, 2021, 36,000 and 116,000 shares, respectively, of common stock were issued under the ESPP. No shares of common stock were issued during the three and nine months ended September 30, 2020 as the ESPP was adopted in September 2020.

Stock-Based Compensation Expense

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Cost of revenue	$ 64	$ 142	$ 201	$ 181
Research and development	760	3,074	2,568	3,326
Sales and marketing	1,207	2,645	4,001	2,828
General and administrative	833	8,047	5,883	8,836
Total stock-based compensation expense	$ 2,864	$ 13,908	$ 12,653	$ 15,171

Stock Options with Performance and Market Conditions

As of December 31, 2020, the Company had 1,933,000 outstanding stock options with performance and market-based vesting conditions. The options vest over the requisite service period if the Company achieves both (i) a performance condition tied to a liquidity event, which includes the effectiveness of an IPO, and (ii) certain market conditions, provided the optionee is providing services on the date of the event. As of September 30, 2021, all outstanding stock options with performance and market-based vesting conditions were fully vested and the related stock-based compensation expense was recognized in full.

For the nine months ended September 30, 2021, the Company recorded stock-based compensation expense of $4.3 million, related to these stock options. For the three months ended September 30, 2021, the Company reversed stock-based compensation expense of $0.1 million related to these stock options due to forfeitures. Stock-based compensation expense of $13.4 million related to these stock options was recognized for the three and nine months ended September 30, 2020 as the performance vesting condition was satisfied upon the closing of the IPO in September 2020.

9. Income Taxes

For each of the three and nine months ended September 30, 2021 and 2020, the Company incurred an income tax provision of an insignificant amount. 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 Attributable to Common Stockholders

A reconciliation of the numerator and denominator used in the calculation of basic and diluted net loss per share attributable to common stockholders is as follows (in thousands, except per share amounts):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Numerator:				
Net loss	$ (30,470)	$ (42,294)	$ (90,703)	$ (89,449)
Adjustment to redemption value on redeemable convertible preferred stock	—	—	—	(362)
Deemed dividend on settlement of accrued dividend	—	—	—	42,530
Net loss attributable to common stockholders, basic and diluted	$ (30,470)	$ (42,294)	$ (90,703)	$ (47,281)
Denominator:				
Weighted-average shares of common stock, basic and diluted	46,588	12,299	46,252	7,508
Net loss per share attributable to common stockholders, basic and diluted	$ (0.65)	$ (3.44)	$ (1.96)	$ (6.30)

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Stock options to purchase common stock	3,728	4,742	3,728	4,742
Warrant to purchase common stock	63	63	63	63
Restricted stock units	542	—	542	—
Shares committed under ESPP	10	5	10	5
Total	4,343	4,810	4,343	4,810

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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020 filed with the Securities and Exchange Commission ("SEC") on March 22, 2021 ("2020 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 enables Tablo to serve as a dialysis clinic on wheels and allows providers to standardize to a single technology platform from the hospital to the home. Tablo is also intelligent and connected, with automated documentation and the ability to integrate with electronic medical record reporting, along with streamlined remote machine management designed to maximize 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 U.S. Food and Drug Administration ("FDA") for use in the hospital, clinic or home setting.

We designed Tablo from the ground up to be a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. Tablo is comprised of a compact console with integrated water purification, on-demand dialysate production and a simple-to-use touchscreen interface. With Tablo, we are bringing data to dialysis. Tablo is built to live in a connected setting with cloud-based system monitoring, patient analytics, remote treatment monitoring and clinical recordkeeping and the ability to activate new capabilities and enhancements through wireless software updates. Tablo's data analytics and connectivity also enable predictive and preventative maintenance designed to maximize machine uptime. Unlike existing hemodialysis machines, which have limited clinical versatility across care settings and are generally burdened by specialized and expensive infrastructure, Tablo is a single enterprise dialysis solution that can be seamlessly utilized across different care settings and for multiple clinical needs.

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 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. While the COVID-19 pandemic has presented opportunities to demonstrate the real-world benefits of Tablo over traditional machines, we believe these benefits, in addition to the other advantages of Tablo, are continuing to drive customer purchasing decisions.

Tablo is also well suited for home-based dialysis. Tablo was cleared by the FDA for use in patients with acute and/or chronic renal failure in September 2014. Subsequently, on March 31, 2020, Tablo was cleared by the FDA for patient use in the home. Our ability to reduce training time, patient dropout, preparation and set up time, and the total treatment time 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 and grow this market successfully, we are focused 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 will also be collecting 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 September 30, 2021, our sales organization is comprised of 34 capital sales team members, responsible for generating new customer demand for Tablo, and 77 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 88 members provides maintenance services and product support to Tablo customers. The same sales organization and field service team drive Tablo penetration in both the acute and home markets. We believe the ability to leverage one team to serve both markets will result in significant productivity and cost optimization as we continue to scale our business.

We are continuing to execute a well-defined strategy designed to expand gross margins. First, we have successfully begun production at our own console manufacturing facility. Second, we are adding a second-source contract manufacturer for our cartridges to help gain higher efficiency and lower material and logistics cost. 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.

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 revenue via annual service contracts and shipping and handling charged to customers. Our total revenue was $26.3 million and $13.8 million for the three months ended September 30, 2021 and 2020, respectively, and $74.5 million and $32.7 million for the nine months ended September 30, 2021 and 2020, respectively.

For the three months ended September 30, 2021 and 2020, we incurred net losses of $30.5 million and $42.3 million, respectively, and for the nine months ended September 30, 2021 and 2020, we incurred net losses of $90.7 million and $89.4 million, respectively. As of September 30, 2021, we had an accumulated deficit of $584.8 million.

On September 17, 2020, we completed our initial public offering ("IPO"), in which we sold 10,293,777 shares of common stock (which included 1,342,666 shares that were offered and sold pursuant to the full exercise of the IPO underwriters' option to purchase additional shares in connection with the IPO) at a price to the public of $27.00 per share. We received aggregate net proceeds of approximately $254.8 million after deducting offering costs, underwriting discounts and commissions of approximately $23.1 million. Upon the closing of the IPO, all of our outstanding redeemable convertible preferred stock automatically converted into shares of common stock.

On April 13, 2021, we completed a follow-on public offering and sold 2,945,864 shares of our common stock (which included 445,864 shares that were offered and sold pursuant to the full exercise of the underwriters' option to purchase additional shares) at a price to the public of $53.50 per share. We received aggregate net proceeds of approximately $149.1 million after deducting offering costs, underwriting discounts and commissions of $8.5 million.

Impacts of the COVID-19 pandemic

We believe that the COVID-19 pandemic has highlighted the limitations of traditional machines and the benefits of Tablo, driving an increase in demand for Tablo during 2020. We also believe the advantages of Tablo highlighted by the pandemic are now embedded as one of the many factors driving our customers' purchasing decisions and do not expect to experience significant revenue driven solely by COVID-19 in future periods. However, the duration and extent of the COVID-19 pandemic remain uncertain, particularly in light of ongoing vaccination efforts and emerging variant strains of the virus, and we cannot predict with certainty the ultimate impact of the COVID-19 pandemic and related containment measures on our business.

In order to operate in a safe manner, we continue to monitor and follow the latest health and safety guidelines of the U.S. Centers for Disease Control and Prevention, Occupational Safety and Health Administration, and local and state public health departments where we operate. These guidelines continue to change in light of local circumstances related to vaccine availability, population vaccination rates and emerging variant strains of the virus (including the Delta variant which appears to be highly transmissible). For employees working on-site, we continue to follow masking protocols consistent with evolving health and safety guidelines, facilitate social distancing and practice increased sanitizing standards. We have strongly encouraged all of our employees to get vaccinated, and during the third quarter of 2021, adopted a policy requiring our customer-facing and on-site employees to be fully vaccinated by October 2021, subject to medical or religious exemptions. Additionally, we continue to provide vaccination site information and COVID-19 testing at our facilities. We are actively supporting remote work arrangements, while planning for a more structured return to office in late 2021 to increase productive collaboration while helping to ensure employee safety. Lastly, we have created a business continuity plan and incident management team to respond quickly and effectively to changes in order to offer customers uninterrupted products, services and support while safeguarding the best interest of employees, suppliers and stockholders.

Our business may also be impacted by an escalation or a continuation of the 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 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 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. These supply chain disruptions have escalated during the fourth quarter of 2021, 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. 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 operation.

How long the pandemic, and measures intended to contain the spread of COVID-19, will continue remains uncertain and depends on ongoing developments, including but not limited to any resurgences of the virus including emerging variant strains such as the Delta variant, federal, state and local government actions taken in response, and continued availability, effectiveness and public acceptance of COVID-19 vaccines. Additionally, the duration and severity of disruptions in the global supply chain, largely driven by high demand as the economy reopens and the ongoing impact of the pandemic, also remain uncertain and depend on various factors, including the effectiveness of recent government actions intended to mitigate these disruptions. As a result, we cannot predict what effect COVID-19, the associated containment measures and the related supply chain disruptions will ultimately have on our business and results of operations, or on our suppliers and vendors, in particular for any of our suppliers and vendors that may not qualify as essential businesses and suffer more significant or lengthier disruptions to their business operations. 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.

Results of Operations

The following table summarizes our results of operations for the three and nine months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Revenue:				
Product revenue	$ 21,824	$ 10,812	$ 60,662	$ 26,435
Service and other revenue	4,494	2,944	13,788	6,253
Total revenue	26,318	13,756	74,450	32,688
Cost of revenue:				
Cost of product revenue	20,526	17,265	63,180	42,118
Cost of service and other revenue	2,846	1,617	6,983	4,024
Total cost of revenue	23,372	18,882	70,163	46,142
Gross profit	2,946	(5,126)	4,287	(13,454)
Operating expenses:				
Research and development	9,729	9,175	25,331	21,066
Sales and marketing	15,726	13,344	42,079	29,870
General and administrative	7,629	13,088	26,597	21,462
Total operating expenses	33,084	35,607	94,007	72,398
Loss from operations	(30,138)	(40,733)	(89,720)	(85,852)
Interest income and other income (expense), net	99	(3)	375	524
Interest expense	(431)	(428)	(1,284)	(2,461)
Change in fair value of redeemable convertible preferred stock warrant liability	—	437	—	(93)
Loss on extinguishment of term loan	—	(1,567)	—	(1,567)
Loss before provision for income taxes	(30,470)	(42,294)	(90,629)	(89,449)
Provision for income taxes	—	—	74	—
Net loss	$ (30,470)	$ (42,294)	$ (90,703)	$ (89,449)

Comparison of the Three and Nine Months Ended September 30, 2021 and 2020

Revenue

(dollars in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Change $	Change %	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Change $	Change %
Revenue:								
Product revenue	$ 21,824	$ 10,812	$ 11,012	102%	$ 60,662	$ 26,435	$ 34,227	129%
Service and other revenue	4,494	2,944	1,550	53%	13,788	6,253	7,535	121%
Total revenue	$ 26,318	$ 13,756	12,562	91%	$ 74,450	$ 32,688	41,762	128%

Product revenue increased by $11.0 million, or 102% for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020, driven by a $6.4 million increase in consoles revenue and a $4.6 million increase in consumables revenue. The increase in consoles revenue was driven by new customer adoption, fleet expansion across existing customer sites, and higher average selling prices and a $0.7 million increase in console leasing revenue. The increase in consumables revenue was driven by the growth in our console installed base.

Product revenue increased by $34.2 million, or 129% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020, driven by a $24.8 million increase in consoles revenue and a $9.4 million increase in consumables revenue. The increase in consoles revenue was driven by new customer adoption, fleet expansion across existing customer sites, higher average selling prices and a $2.0 million increase in console leasing revenue. The increase in consumables revenue was driven by the growth in our console installed base.

Service and other revenue increased for the three and nine months ended September 30, 2021 from the three and nine months ended September 30, 2020. The increase was primarily due to services associated with the growth in our console installed base, including leased consoles.

Cost of Revenue, Gross Profit and Gross Margin

(dollars in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Change $	Change %	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Change $	Change %
Cost of revenue:								
Cost of product revenue	$ 20,526	$ 17,265	$ 3,261	19 %	$ 63,180	$ 42,118	$ 21,062	50 %
Cost of service and other revenue	2,846	1,617	1,229	76 %	6,983	4,024	2,959	74 %
Total cost of revenue	$ 23,372	$ 18,882	4,490	24 %	$ 70,163	$ 46,142	24,021	52 %
Gross profit	2,946	(5,126)	8,072	157 %	4,287	(13,454)	17,741	132 %
Gross margin	*11.2* %	*(37.3)* %			*5.8* %	*(41.2)* %		

Cost of product revenue increased by $3.3 million, or 19% for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. This increase was primarily due to higher console and consumable volume of $8.9 million. This was offset by a $4.1 million reduction in product costs and a $1.5 million decrease in manufacturing overhead.

Cost of product revenue increased by $21.1 million, or 50% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. This increase was primarily due to higher console and consumable volume of $36.1 million and higher depreciation expense for leased consoles of $0.5 million. This was offset by a $14.2 million reduction in product costs and a $1.4 million decrease in manufacturing overhead.

Cost of service and other revenue increased for the three and nine months ended September 30, 2021 as compared to the three and nine months ended September 30, 2020. This increase was primarily due to additional headcount costs in our service department, which were absorbed across our larger installed base.

Gross profit increased by $8.1 million, or 157% for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The gross margin percentage improved by 48.5 percentage points for the three months ended September 30, 2021, as compared to the three months ended September 30, 2020, driven primarily by the impact of our cost reduction activities and higher average selling prices.

Gross profit increased by $17.7 million, or 132% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The gross margin percentage improved by 47.0 percentage points for the nine months ended September 30, 2021, as compared to the nine months ended September 30, 2020, driven primarily by the impact of our cost reduction activities and higher average selling prices.

Operating Expenses

(dollars in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Change $	Change %	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Change $	Change %
Operating expenses:								
Research and development	$ 9,729	$ 9,175	$ 554	6 %	$ 25,331	$ 21,066	$ 4,265	20 %
Sales and marketing	15,726	13,344	2,382	18 %	42,079	29,870	12,209	41 %
General and administrative	7,629	13,088	(5,459)	(42)%	26,597	21,462	5,135	24 %
Total operating expenses	$ 33,084	$ 35,607	(2,523)	(7)%	$ 94,007	$ 72,398	21,609	30 %

Research and development expenses increased by $0.6 million, or 6% for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The increase was primarily due to a $1.7 million increase in consulting services. The increase was partially offset by a $1.2 million net decrease in compensation and personnel costs, which includes a $1.1 million increase in compensation offset by a $2.3 million decrease in stock-based compensation expense due to the one-time cumulative expense related to stock options with performance and market-based vesting conditions in 2020.

Research and development expenses increased by $4.3 million, or 20% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The increase was primarily due to a $2.6 million increase in consulting services and a $2.0 million net increase in compensation and personnel costs which includes a $2.8 million increase in compensation offset by a $0.8 million decrease in stock-based compensation expense due to the one-time cumulative expense related to stock options with performance and market-based vesting conditions in 2020. The increases were partially offset by a $0.3 million decrease in supplies and materials.

Sales and marketing expenses increased by $2.4 million, or 18% for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The increase was primarily due to a $1.0 million net increase in compensation and personnel costs, which includes a $2.4 million increase in compensation offset by a $1.4 million decrease in stock-based compensation expense due to the one-time cumulative expense related to stock options with performance and market-based vesting conditions in 2020, a $0.6 million increase in travel expenses, a $0.5 million increase in allocated costs for facilities and information technology to support the general expansion of our operations, a $0.1 million increase in freight expenses and a $0.1 million increase in clinical sales consulting services.

Sales and marketing expenses increased by $12.2 million, or 41% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The increase was primarily due to a $7.9 million increase in compensation and personnel costs, which includes a $1.2 million increase in stock-based compensation expense, a $2.1 million increase in clinical sales consultant services, a $1.0 million increase in allocated costs for facilities and information technology to support the general expansion of our operations, a $0.8 million increase in travel expenses and a $0.3 million increase in freight expenses.

General and administrative expenses decreased by $5.5 million, or 42% for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. The decrease was primarily due to a $5.6 million net decrease in compensation and personnel costs, which includes a $7.2 million decrease in stock-based compensation expense due to the one-time cumulative expense related to stock options with performance and market-based vesting conditions in 2020 which offset by a $1.6 million increase compensation, and a $0.7 million decrease in outside services costs. The decrease was partially offset by a $0.6 million increase in insurance costs and a $0.1 million increase in allocated costs for facilities and information technology to support the general expansion of our operations.

General and administrative expenses increased by $5.1 million, or 24% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The increase was primarily due to a $2.4 million increase in insurance costs, a $1.2 million net increase in compensation and personnel costs, which includes a $4.2 million increase in compensation offset by a $3.0 million decrease in stock-based compensation expense due to the one-time cumulative expense related to stock options with performance and market-based vesting conditions in 2020, a $0.8 million increase in professional and consulting services and a $0.7 million increase in allocated costs for facilities and information technology to support the general expansion of our operations.

Other Income (Expense), Net

(dollars in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020	Change $	Change %	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020	Change $	Change %
Other Income (Expense), Net:								
Interest income and other income (expense), net	$ 99	$ (3)	$ 102	(3,400)%	$ 375	$ 524	$ (149)	(28)%
Interest expense	(431)	(428)	(3)	1%	(1,284)	(2,461)	1,177	(48)%
Change in fair value of redeemable convertible preferred stock warrant liability	—	437	(437)	*	—	(93)	93	*
Loss on extinguishment of term loan	—	(1,567)	1,567	*	—	(1,567)	1,567	*
Total other expense, net	$ (332)	$ (1,561)	1,229	(79)%	$ (909)	$ (3,597)	2,688	(75)%

** Not meaningful*

Interest income and other income (expense), net increased by $0.1 million for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020. This increase was primarily due to a higher average balance in money market funds and short-term investment securities in the three months ended September 30, 2021.

Interest income and other income (expense), net decreased by $0.1 million, or 28% for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The decrease was primarily due to a $0.4 million decrease in interest income driven by lower interest rates during 2021. This decrease was partially offset by a $0.3 million value added taxes refund primarily related to startup costs in our new manufacturing facility received during 2021.

Interest expense slightly increased for the three months ended September 30, 2021 as compared to the three months ended September 30, 2020 due to accretion of the SVB Term Loan.

Interest expense decreased for the nine months ended September 30, 2021 as compared to the nine months ended September 30, 2020. The decrease was driven primarily by a lower interest rate under the SVB Term Loan as compared to the rate under the Perceptive Term Loan, which we voluntarily repaid in July 2020.

The change in the fair value of redeemable convertible preferred stock warrant liability was driven by the changes in assumptions used to value the warrant liability. Upon the closing of our IPO in September 2020, all of our outstanding redeemable convertible preferred stock warrants were either exercised into common stock or automatically converted into warrants to purchase common stock. Accordingly, we have ceased to incur the change in the fair value of redeemable convertible preferred stock warrant liability as the entire redeemable convertible preferred stock warrant liability was reclassified to additional paid-in capital.

The loss on extinguishment of term loan of $1.6 million was recognized for the repayment of the Perceptive Team Loan in July 2020, which included early repayment and exit fees.

Liquidity and Capital Resources

Sources of Liquidity

As of September 30, 2021, we had cash, cash equivalents and short-term investments of $373.0 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 $406.4 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 and issuances of debt. In September 2020, we completed our IPO for aggregate net proceeds of approximately $254.8 million (inclusive of the full exercise of the underwriters' option to purchase additional shares), net of offering costs, underwriter discounts and commissions of $23.1 million. In April 2021, we completed a follow-on public offering for aggregate net proceeds of approximately $149.1 million, after deducting offering costs, underwriting discounts and commissions of $8.5 million.

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 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, will be sufficient to meet our anticipated needs for at least the next 12 months from the date of this Quarterly Report.

Cash Flows Summary

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

	Nine Months Ended September 30, 2021	Nine Months Ended September 30, 2020
Net cash (used in) provided by:		
Operating activities	$ (97,588)	$ (73,175)
Investing activities	(126,089)	(6,411)
Financing activities	159,213	386,555
Net (decrease) increase in cash, cash equivalents and restricted cash	$ (64,464)	$ 306,969

Operating Activities

The net cash used in operating activities of $97.6 million for the nine months ended September 30, 2021 was due to a net loss of $90.7 million and a net cash outflow from the change in our operating assets and liabilities of $26.5 million, which were partially offset by adjustments for stock-based compensation expense of $12.7 million, depreciation and amortization of $3.9 million, accretion of discount on investments of $1.2 million, non-cash lease expense of $0.8 million, provision for inventories of $0.8 million, and non-cash interest expense of $0.4 million. The net cash outflow from operating assets and liabilities was primarily due to an increase in inventories of $17.9 million due to the timing of inventory purchases including advance purchases of inventory due to the anticipated demand and to mitigate supply chain disruptions, which partially related to COVID-19, an increase in accounts receivable of $12.8 million due to timing of collections, a decrease in account payable of $2.1 million due to timing of vendor payments, and a decrease in operating lease liabilities of $0.6 million. The net cash outflow from operating assets and liabilities was partially offset by an increase in accrued expenses and other current liabilities of $3.5 million, an increase in deferred revenue of $1.6 million due to the growth of our business, an increase in accrued payroll and related benefits of $0.9 million, a decrease in prepaid expenses and other assets of $0.7 million, and an increase in accrued warranty liability of $0.3 million.

Net cash used in operating activities of $73.2 million for the nine months ended September 30, 2020 was due to a net loss of $89.4 million and a net change in our net operating assets and liabilities of $3.2 million, partially offset by adjustments for stock-based compensation of $15.2 million, loss on extinguishment of term loan of $1.6 million, depreciation and amortization of $1.2 million, non-cash interest expense of $0.5 million, non-cash lease expense of $0.4 million, provision for inventories of $0.4 million, and change in fair value of redeemable convertible preferred stock warrant liability of $0.1 million. The net cash outflow from operating assets and liabilities was primarily due to an increase in inventories of $9.2 million due to the timing of inventory purchases including advance purchases of inventory due to anticipated demand, an increase in prepaid expenses and other assets of $5.4 million, and an increase in accounts receivable of $3.2 million due to timing of collections. The net cash outflow from operating assets and liabilities was partially offset by an increase in accrued expenses and other current liabilities of $5.1 million consistent with the growth of our business, an increase in accrued payroll and related benefits of $3.9 million due to an increase in headcount, an increase in deferred revenue of $3.7 million, and an increase in accrued warranty liability of $1.6 million and an increase in accounts payable of $0.4 million due to timing of vendor payments.

Investing Activities

The net cash used in investing activities of $126.1 million for the nine months ended September 30, 2021 was due primarily to the purchases of investment securities of $148.1 million and the purchases of property and equipment of $2.3 million, partially offset by the sales and maturities of investment securities of $24.3 million.

Net cash used in investing activities of $6.4 million for the nine months ended September 30, 2020 was due primarily to the purchases of short-term investments of $32.9 million and the purchases of property and equipment of $6.4 million, partially offset by the sales and maturities of short-term investments of $32.9 million.

Financing Activities

The net cash provided by financing activities of $159.2 million for the nine months ended September 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 $10.1 million from employee exercises of stock options and employee stock purchase plan purchases.

Net cash provided by financing activities of $386.6 million for the nine months ended September 30, 2020 was due primarily to the net proceeds of $255.7 million from the issuance of our common stock in our IPO, net of issuance costs paid to date, the net proceeds of $126.8 million from the issuance of our Series E redeemable convertible preferred stock, the net proceeds of $29.6 million from borrowings on the SVB Loan and Security Agreement, proceeds of $4.3 million from the exercise of the Series C redeemable convertible preferred stock warrants, and proceeds of $1.1 million from the issuance of common stock from exercises of stock options, partially offset by the cash outflow of $31.0 million in repayment of Perceptive Loan which included early prepayment and exit fees.

Contractual Obligations and Commitments

During the three and nine months ended September 30, 2021, 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 2020 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 2020 Annual Report. For additional information, please refer to Note 2 to our unaudited condensed financial statements in this Quarterly Report.

Emerging Growth Company Status

We are an emerging growth company, as defined in the Jumpstart Our Business Startups Act ("JOBS Act"). Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Because (i) the aggregate worldwide market value of our voting common stock held by non-affiliates (or "public float") exceeded $700 million on June 30, 2021, (ii) we will have been subject to the reporting requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended ("Exchange Act") for at least twelve calendar months, (iii) we have previously filed an annual report under Section 13(a) or 15(d) of the Exchange Act and (iv) we are not eligible for smaller reporting company status because we exceed the public float and revenue threshold for such status, we will qualify as a "large accelerated filer" under Rule 12b-2 of the Exchange Act as of the end of the current fiscal year. As a large accelerated filer, we will no longer qualify as an emerging growth company.

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

Interest Rate Risk

Our cash, cash equivalents, restricted cash and short-term investments are held in bank deposits, money market funds, U.S. Treasury and debt securities. Such interest-earning instruments carry a degree of interest rate risk. The goals of our investment policy are liquidity and capital preservation; we do not enter into investments for trading or speculative purposes and have not used any derivative financial instruments to manage our interest rate exposure. We believe that we do not have any material exposure to changes in the fair value of these assets as a result of changes in interest rates due to the relative short-term nature of our cash, cash equivalents and short-term investments.

As of September 30, 2021, we had $30.0 million in variable rate debt outstanding. The SVB Term Loan matures on November 1, 2025, with interest-only monthly payments until June 2023. The term loan accrues interest at a rate per annum equal to the greater of (A) one-half of one percent (0.50%) above the Prime Rate as reported in the Wall Street Journal then in effect (which shall not be less than zero) and (B) three and three-quarters of one percent (3.75%). An immediate 100 basis point change in the prime rate would not have a material impact on our debt-related obligations, financial position or results of operations.

Foreign Currency Exchange Risk

Our expenses are generally denominated in U.S. dollars. However, as certain of our Mexico-based manufacturing operations incur costs that are denominated in Mexican Pesos (“MXN”), we are exposed to the risk of currency fluctuations between the U.S. dollar and MXN. To date, foreign currency transaction gains and losses have not been material to our financial statements.

Unfavorable changes in foreign exchange rates versus the U.S. dollar could increase our product costs, thus reducing our gross profit. We have not engaged in the hedging of foreign currency transactions to date, although we may choose to do so in the future. We do not believe that an immediate 10% increase or decrease in the relative value of the U.S. dollar to other currencies would have a material effect on our operating results or financial condition.

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, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and our 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 period covered by this Quarterly Report.

Changes in Internal Control over Financial Reporting

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

PART II—OTHER INFORMATION

Item 1. Legal Proceedings.

From time to time we may become involved in legal proceedings or investigations, which could have an adverse impact on our reputation, business and financial condition and divert the attention of our management from the operation of our business. We are not presently a party to any legal proceedings that, if determined adversely to us, would individually or taken together have a material adverse effect on our business, results of operations, financial condition or cash flows.

Item 1A. Risk Factors.

You should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 2020 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 March 31, 2021 ("Q1 2021 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 2020 Annual Report, as updated by our Q1 2021 Quarterly Report, except as set forth below. The risks described in our 2020 Annual Report and our Q1 2021 Quarterly Report as updated below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial, may also arise and materially impact our business. If any of these risks occur, our business, results of operations and financial condition could be materially and adversely affected and the trading price of our common stock could decline.

We depend upon third-party suppliers, including contract manufacturers and single-source suppliers, making us vulnerable to supply problems and price fluctuations.

We rely on third-party suppliers, including in some instances single-source suppliers, to provide us with certain components of Tablo. The number of suppliers feeding into Tablo console production is in excess of 250 worldwide. We consider approximately 9% of these suppliers, located in the United States, Europe and China, as critical providers of components such as pumps, motors, valves and PCBA boards. While we are undertaking a second source qualification process for the majority of these critical components, we may not ultimately be successful in securing second sourcing for all of them.

In addition, we purchase supplies through purchase orders and do not have long-term supply agreements with, or guaranteed commitments from, our suppliers, including single-source suppliers. Moreover, at present, we rely on contract manufacturers for the production of the Tablo cartridge. Many of our suppliers and contract manufacturers are not obligated to perform services or supply products for any specific period, in any specific quantity or at any specific price, except as may be provided in a particular purchase order. We depend on our suppliers and contract manufacturers to provide us and our customers with materials in a timely manner that meet our and their quality, quantity and cost requirements. These suppliers and contract manufacturers may encounter problems during manufacturing for a variety of reasons, including as a result of public health crises such as the ongoing COVID-19 pandemic, labor disputes, work stoppages, damage or interruption from fires, severe weather or other natural disasters, vandalism, terrorism or other political hostilities, any of which could delay or impede their ability to meet our demand. These suppliers and contract manufacturers may cease producing the components we purchase from them or otherwise decide to cease doing business with us. Further, we maintain limited volumes of inventory from most of our suppliers and contract manufacturers. If we inaccurately forecast demand for finished goods, we may be unable to meet customer demand which could harm our competitive position and reputation. Further, if we fail to effectively manage our relationships with our suppliers and contract manufacturers, we may be required to change suppliers or contract manufacturers. While we believe replacement suppliers exist for all materials, components and services necessary to continue manufacturing our Tablo system, establishing additional or replacement suppliers for any of these materials, components or services could be time-consuming and expensive, may result in interruptions in our operations and product delivery, may affect the performance specifications of our Tablo system or could require that we modify Tablo's design. Even if we are able to find replacement suppliers, we will be required to verify that the new supplier maintains facilities, procedures and operations that comply with our quality expectations and applicable regulatory requirements. Any of these events could require that we obtain a new regulatory authority approval before we implement the change, which could result in further delay and which may not be obtained at all. If our third-party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers capable of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our Tablo system, the supply of our products to customers and the development of any future products will be delayed, limited or prevented, which could have material adverse effect on our business, financial condition and results of operations.

For example, the COVID-19 pandemic has disrupted the operations of certain of our third-party suppliers, resulting in increased lead-times, higher component costs and lower allocations for our purchases of some components (including certain critical components) and, in certain cases, requiring us to procure materials from alternative sources 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. However, 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, any of our critical single-source component providers, or the facility we operate in Tijuana, Mexico in collaboration with our outsourced business administration service provider, Tacna, are more severely impacted by the pandemic and associated containment measures. If these contract manufacturers or suppliers experience disruptions as a result of the pandemic that impede their ability to meet our demand in a timely manner, we may be unable to find alternative sources of supply, be required to pay higher prices, or fail to meet customer demand, any of which would harm our business.

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. These supply chain disruptions have escalated during the fourth quarter of 2021, 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. 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 operation.

We have significant customer concentration, with a limited number of customers accounting for a substantial portion of our revenues.

For the nine months ended September 30, 2021, one customer and a federal health department customer accounted for 31% and 18% of our revenue, respectively. There are risks whenever a large percentage of total revenues are concentrated with a limited number of customers. It is not possible for us to predict the level of demand for Tablo that will be generated by any of these customers in the future. In addition, revenues from these larger customers may fluctuate from time to time based on these customers’ business needs and customer experience, the timing of which may be affected by market conditions or other factors outside of our control. Furthermore, because our business model consists of an upfront capital purchase by our customers, and relatively lower recurring revenue from future sales of consumables and services, revenues from these larger customers may not represent a substantial portion of our revenues in future periods. These customers could also potentially pressure us to reduce the prices we charge for Tablo, which could have an adverse effect on our margins and financial position and could negatively affect our revenues and results of operations. If any of our largest customers terminates its relationship with us, such termination could negatively affect our revenues and results of operations.

Performance issues, service interruptions or price increases by our shipping carriers and warehousing providers could adversely affect our business and harm our reputation and ability to provide our services on a timely basis.

Expedited, reliable shipping and secure warehousing are essential to our operations. We rely heavily on providers of transport services for reliable and secure point-to-point transport of our Tablo system to our customers and for tracking of these shipments, and from time to time require warehousing for our products. Should a carrier encounter delivery performance issues such as loss, damage or destruction of any systems, it would be costly to replace such systems in a timely manner and such occurrences may damage our reputation and lead to decreased demand for our Tablo system and increased cost and expense to our business. In addition, any significant increase in shipping or warehousing rates could adversely affect our operating margins and results of operations. For example, 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 freight ground carriers, resulting in increased freight costs. If freight costs continue to escalate and/or remain high for a sustained period of time, our operating margins and results of operations would be adversely impacted. Similarly, strikes, severe weather, natural disasters or other service interruptions affecting delivery or warehousing services we use would adversely affect our ability to process orders for our Tablo system on a timely basis.

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: November 3, 2021	By:	/s/ Leslie Trigg
		Leslie Trigg President and Chief Executive Officer (*Principal Executive Officer*)
Date: November 3, 2021	By:	/s/ Nabeel Ahmed
		Nabeel Ahmed Chief Financial Officer (*Principal Financial and Accounting Officer*)

Exhibit 31.1

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

I, Leslie Trigg, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2021

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

Exhibit 31.2

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

I, Nabeel Ahmed, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: November 3, 2021

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

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

In connection with the Quarterly Report of Outset Medical, Inc. (the "Company") on Form 10-Q for the period ending September 30, 2021, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to her/his knowledge:

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

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

November 3, 2021	By:	/s/ Leslie Trigg
		Leslie Trigg
		Chief Executive Officer
		(*Principal Executive Officer*)
November 3, 2021	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.