

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

FORM 10-Q

(Mark One)

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

For the quarterly period ended March 31, 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
(State or other jurisdiction of
incorporation or organization)
3052 Orchard Dr.
San Jose, California
(Address of principal executive offices)

20-0514392
(I.R.S. Employer
Identification No.)

95134
(Zip Code)

Registrant's telephone number, including area code: (669) 231-8200

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	OM	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

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 April 30, 2021, the registrant had 45,981,392 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)

	March 31, 2021 <u>(Unaudited)</u>	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 251,767	\$ 294,972
Short-term investments	25,717	19,898
Accounts receivable, net	12,110	6,468
Inventories	24,554	18,384
Prepaid expenses and other current assets	7,578	6,189
Total current assets	321,726	345,911
Restricted cash	33,311	33,311
Property and equipment, net	15,548	14,998
Operating lease right-of-use assets	8,004	8,253
Other assets	1,240	1,356
Total assets	<u>\$ 379,829</u>	<u>\$ 403,829</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 6,651	\$ 4,948
Accrued compensation and related benefits	12,602	16,845
Accrued expenses and other current liabilities	8,183	7,903
Accrued warranty liability	2,860	2,913
Deferred revenue, current	3,540	3,201
Operating lease liabilities, current	984	882
Total current liabilities	34,820	36,692
Accrued interest, noncurrent	359	240
Deferred revenue, noncurrent	536	570
Operating lease liabilities, noncurrent	7,773	8,044
Term loan, noncurrent	29,696	29,674
Total liabilities	<u>73,184</u>	<u>75,220</u>
Commitments and contingencies (Note 6)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of March 31, 2021 and December 31, 2020	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of March 31, 2021 and December 31, 2020; 42,888 and 42,722 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	43	43
Additional paid-in capital	830,694	822,624
Accumulated other comprehensive (loss) income	(8)	1
Accumulated deficit	(524,084)	(494,059)
Total stockholders' equity	<u>306,645</u>	<u>328,609</u>
Total liabilities and stockholders' equity	<u>\$ 379,829</u>	<u>\$ 403,829</u>

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

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

	Three Months Ended	
	March 31,	
	2021	2020
Revenue:		
Product revenue	\$ 18,210	\$ 5,926
Service and other revenue	4,706	1,264
Total revenue	<u>22,916</u>	<u>7,190</u>
Cost of revenue:		
Cost of product revenue	20,577	9,562
Cost of service and other revenue	2,050	1,192
Total cost of revenue	<u>22,627</u>	<u>10,754</u>
Gross profit	289	(3,564)
Operating expenses:		
Research and development	7,570	5,838
Sales and marketing	13,149	7,282
General and administrative	9,246	3,526
Total operating expenses	<u>29,965</u>	<u>16,646</u>
Loss from operations	(29,676)	(20,210)
Interest income and other income, net	112	460
Interest expense	(422)	(1,001)
Change in fair value of redeemable convertible preferred stock warrant liability	—	101
Loss before provision for income taxes	<u>(29,986)</u>	<u>(20,650)</u>
Provision for income taxes	39	—
Net loss	<u>\$ (30,025)</u>	<u>\$ (20,650)</u>
Net income (loss) attributable to common stockholders:		
Basic	<u>\$ (30,025)</u>	<u>\$ 3,387</u>
Diluted	<u>\$ (30,025)</u>	<u>\$ 4,161</u>
Net income (loss) per share attributable to common stockholders:		
Basic	<u>\$ (0.70)</u>	<u>\$ 0.77</u>
Diluted	<u>\$ (0.70)</u>	<u>\$ 0.74</u>
Weighted-average shares used in computing net income (loss) per share attributable to common stockholders:		
Basic	<u>42,760</u>	<u>4,388</u>
Diluted	<u>42,760</u>	<u>5,630</u>

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

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

	Three Months Ended	
	March 31,	
	2021	2020
Net loss	\$ (30,025)	\$ (20,650)
Other comprehensive loss:		
Unrealized loss on available-for-sale securities	(9)	(35)
Comprehensive loss	<u>\$ (30,034)</u>	<u>\$ (20,685)</u>

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 Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
Balance as of December 31, 2020	—	\$ —	42,722	\$ 43	\$ 822,624	\$ 1	\$ (494,059)	\$ 328,609
Issuance of common stock through employee stock purchase plan	—	—	80	—	1,838	—	—	1,838
Stock option exercises	—	—	86	—	380	—	—	380
Stock-based compensation expense	—	—	—	—	5,852	—	—	5,852
Unrealized loss on available-for-sale securities	—	—	—	—	—	(9)	—	(9)
Net loss	—	—	—	—	—	—	(30,025)	(30,025)
Balance as of March 31, 2021	—	\$ —	42,888	\$ 43	\$ 830,694	\$ (8)	\$ (524,084)	\$ 306,645

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 Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount				
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	<u>204,996</u>	<u>\$ 452,273</u>	<u>5,776</u>	<u>\$ 6</u>	<u>\$ 84,877</u>	<u>\$ (13)</u>	<u>\$ (393,217)</u>	<u>\$ (308,347)</u>

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

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

	Three Months Ended March 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (30,025)	\$ (20,650)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	1,246	305
Non-cash lease expense	249	—
Non-cash interest expense	140	200
Accretion of discount on investments, net	60	16
Provision for accounts receivable	5	11
Provision for inventories	115	90
Stock-based compensation expense	5,852	580
Change in fair value of redeemable convertible preferred stock warrant liability	—	(101)
Changes in operating assets and liabilities:		
Accounts receivable	(5,646)	(3,055)
Inventories	(7,247)	824
Prepaid expenses and other assets	(981)	71
Accounts payable	1,613	(1,430)
Accrued payroll and related benefits	(4,244)	(2,726)
Accrued expenses and other current liabilities	164	150
Accrued warranty liability	(53)	71
Deferred revenue	305	751
Operating lease liabilities	(169)	—
Net cash used in operating activities	<u>(38,616)</u>	<u>(24,893)</u>
Cash flows from investing activities:		
Purchases of property and equipment	(919)	(2,799)
Purchases of short-term investments	(25,788)	—
Sales and maturities of short-term investments	19,900	21,958
Net cash (used in) provided by investing activities	<u>(6,807)</u>	<u>19,159</u>
Cash flows from financing activities:		
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	2,218	15
Repayment of finance lease	—	(3)
Net cash provided by financing activities	<u>2,218</u>	<u>126,770</u>
Net (decrease) increase in cash, cash equivalents and restricted cash	(43,205)	121,036
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	<u>\$ 285,078</u>	<u>\$ 158,705</u>
Supplemental cash flow disclosures:		
Cash paid for income taxes	\$ —	\$ —
Cash paid for interest	\$ 282	\$ 800
Cash paid for amounts included in the measurement of operating lease liabilities	\$ 169	\$ —
Supplemental non-cash investing and financing activities:		
Capital expenditures included in accounts payable and accrued expenses	\$ 238	\$ 366
Deemed dividend on settlement of accrued dividend	\$ —	\$ 42,530
Adjustment to redemption value on redeemable convertible preferred stock	\$ —	\$ 362
Issuance of common stock on settlement of accrued dividend	\$ —	\$ 41,763

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

Outset Medical, Inc.
Notes to Condensed Financial Statements

1. Description of Business

Outset Medical, Inc. (the “Company”) was originally incorporated on May 5, 2003 in the state of Delaware under the name Home Dialysis Plus, Ltd. The name of the Company was changed to Outset Medical, Inc. on January 5, 2015. Outset Medical, Inc. is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. The Tablo Hemodialysis System enables dialysis care in acute and chronic settings. 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 (see Note 11 for further discussion).

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 three months ended March 31, 2021 and 2020, the Company incurred a net loss of \$30.0 million and \$20.7 million, respectively. As of March 31, 2021, the Company had an accumulated deficit of \$524.1 million.

As of March 31, 2021, the Company had cash, cash equivalents and short-term investments of \$277.5 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 \$310.8 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 cash generated from revenues from its products and services, as well as the proceeds from the follow-on public offering (see Note 11 for further discussion), will be sufficient to meet its anticipated needs for at least the next 12 months from the issuance date of the accompanying condensed financial statements.

Basis of Presentation

The accompanying condensed financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, that are necessary for the fair statement of the Company’s financial position, results of operations, comprehensive loss and cash flows for the interim periods presented. The financial data and the other financial information disclosed in these notes to the condensed financial statements related to the three-month period are also unaudited. The results of operations for the three months ended March 31, 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 filed with SEC on March 22, 2021.

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 months ended March 31, 2021, there have been no changes to the Company's significant accounting policies as described in its Annual Report on Form 10-K for the fiscal year ended December 31, 2020 that have had a material impact on the Company's condensed financial statements and related notes, except as described below, including under "Recently Adopted Accounting Pronouncements."

Cash, Cash Equivalents and Restricted Cash

As of March 31, 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):

	March 31,	
	2021	2020
Cash and cash equivalents	\$ 251,767	\$ 157,962
Restricted cash	33,311	743
Total cash, cash equivalents and restricted cash	<u>\$ 285,078</u>	<u>\$ 158,705</u>

Fair Value of Financial Instruments

The Company determines the fair value of an asset or liability based on the assumptions that market participants would use in pricing the asset or liability in an orderly transaction between market participants at the measurement date. The identification of market participant assumptions provides a basis for determining what inputs are to be used for pricing each asset or liability.

A fair value hierarchy has been established which gives precedence to fair value measurements calculated using observable inputs over those using unobservable inputs. This hierarchy prioritizes the inputs into three broad levels as follows:

Level 1: Quoted prices in active markets for identical instruments;

Level 2: Other significant observable inputs (including quoted prices in active markets for similar instruments); and

Level 3: Significant unobservable inputs (including assumptions in determining the fair value of certain investments).

The Company's cash and cash equivalents, restricted cash, short-term investments, accounts receivable, accounts payable and accrued liabilities approximate their fair value due to their short maturities. Management believes that its term loan bears interest at the prevailing market rates for instruments with similar characteristics; accordingly, the carrying value of this instrument approximates its fair value.

The Company's investment securities are recorded at fair value based on the fair value hierarchy. Money market funds and U.S. Treasury securities are classified within Level 1 of the fair value hierarchy. Commercial paper, corporate debt and Yankee debt securities are within Level 2 of the fair value hierarchy. Unrealized gains and losses, deemed temporary in nature, are reported as a separate component of accumulated other comprehensive income (loss).

Accrued Warranty Liability

The Company generally provides a one-year warranty for defective parts and workmanship on its Tablo consoles, commencing upon the transfer of title and risk of loss to the customer. The Company accrues the estimated cost of product warranties when it invoices the customer, based on historical experience and expected results. Should actual product failure rates and material usage costs differ from these estimates, revisions to the estimated warranty liability would be required. The Company periodically assesses the adequacy of its recorded product warranty liabilities and adjusts the balance as required. Warranty expense is recorded as a component of cost of product revenue in the accompanying condensed statements of operations.

Contract Liabilities - Deferred Revenue

The timing of revenue recognition may differ from the timing of invoicing to customers. The Company records deferred revenue when revenue is recognized subsequent to invoicing. For multi-year service agreements, the Company generally invoices customers annually at the beginning of each annual coverage period. Deferred revenue that will be recognized during the 12 months following the balance sheet date is recorded as the current portion of deferred revenue and the remaining portion is recorded as noncurrent.

Revenue

The Company's revenue is generated primarily from the sale of its products and services. Product revenue consists primarily of sales of the Tablo console and related consumables, including Tablo cartridges, used in treatment delivery. Service and other revenue consists primarily of revenue generated from consoles service contracts and other revenue from shipping and handling charged to customers.

The Company considers each product and each service contract to be a distinct performance obligation. Revenue is recognized when a performance obligation is satisfied, which occurs when control of the promised products or services is transferred to the customer in an amount that reflects the consideration the Company expects to receive in exchange for those products or services. Revenue from product sales is recognized at a point in time when management has determined that control has transferred to the customer, which is generally when legal title has transferred to the customer. Revenue from service contracts is recognized as the output of the service is transferred to the customer over time, typically evenly over the contract term. Revenue is recognized net of allowances for returns and any taxes collected from customers, which are subsequently remitted to governmental authorities.

The Company's contracts with customers often include promises to transfer multiple products and services to a customer. Determining whether products and services are considered distinct performance obligations that should be accounted for separately versus together may require significant judgment. Judgment is also required to determine the stand-alone selling price (SSP) for each distinct performance obligation. The Company uses an observable price to estimate SSP for items that are sold separately, including customer support agreements. In instances where SSP is not directly observable, such as when the Company does not sell the product or service separately, the Company determines the SSP using information that may include market conditions and other observable inputs. The Company may offer additional goods or services to customers at the inception of customer contracts at prices not at SSP. This may be considered a material right and an additional performance obligation of the contract. SSP is assigned based on the estimated value of the material right.

Costs associated with product sales include commissions. The Company applies the practical expedient to expense the commissions as incurred as the expected amortization period is one year or less. Commissions are recorded as sales and marketing expenses in the accompanying condensed statements of operations.

Operating Lease Arrangements

The Company enters into operating lease arrangements that contain both lease and non-lease elements. The lease element includes Tablo consoles, while non-lease elements include consumables, services and training. Revenue related to such arrangements is allocated to lease and non-lease elements based on their relative SSP. Revenue for the lease element, net of any taxes collected from customers, is recognized on a straight-line basis as product revenue over the lease term, generally three months to one year, in the statements of operations. The costs of the leased Tablo consoles are included in property and equipment, net in the balance sheets and amortized to cost of product revenue.

Shipping and Handling Costs

Shipping and handling charged to customers are recorded as revenue. Shipping and handling costs are expensed as incurred and are included in sales and marketing expenses.

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.

Net Income (Loss) Per Share Attributable to Common Stockholders

The Company follows the two-class method when computing net income (loss) per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net income (loss) per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net income (loss) per share attributable to common stockholders is calculated by dividing the net income (loss) attributable to common stockholders by the weighted-average number of shares of common stock outstanding for the period, without consideration for potential dilutive securities.

Diluted net income (loss) per share is computed by dividing the net income (loss) by the weighted-average number of common shares and common share equivalents of potentially dilutive securities outstanding for the period. For purposes of the diluted net income (loss) per share calculation, redeemable convertible preferred stock, awards under the Company’s equity compensation plan and warrants are considered to be potentially dilutive securities. For periods in which the Company reports net losses, basic net loss per share attributable to common stockholders is the same as diluted net loss per share attributable to common stockholders because the effects of potentially dilutive securities are antidilutive.

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 March 31,	
	2021	2020
Consoles	\$ 14,766	\$ 5,027
Consumables	3,444	899
Total product revenue	18,210	5,926
Service and other revenue	4,706	1,264
Total revenue	\$ 22,916	\$ 7,190

For the three months ended March 31, 2021 and 2020, \$1.3 million and \$0.6 million of consoles revenue were from console operating lease arrangements.

Performance Obligations

As of March 31, 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 \$4.1 million, which is recorded as deferred revenue on the Company’s condensed balance sheets. Of that amount, \$3.6 million will be recognized as revenue during the next 12 months and approximately \$0.5 million thereafter.

Contract Liabilities

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. The following table summarizes the Company’s contract liabilities (in thousands):

	March 31, 2021	December 31, 2020
Deferred revenue, current	\$ 3,540	\$ 3,201
Deferred revenue, noncurrent	536	570
Total deferred revenue	\$ 4,076	\$ 3,771

Revenue recorded during the three months ended March 31, 2021 included \$2.4 million 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):

March 31, 2021					
	Valuation Hierarchy	Amortized Costs	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Aggregate Fair Value
Assets:					
Cash equivalents:					
Money market funds	Level 1	\$ 50,147	\$ —	\$ —	\$ 50,147
Short-term investments:					
Commercial paper	Level 2	13,286	—	—	13,286
Corporate debt	Level 2	10,416	—	(6)	10,410
Yankee debt securities	Level 2	2,023	—	(2)	2,021
Total cash equivalents and short-term investments		<u>\$ 75,872</u>	<u>\$ —</u>	<u>\$ (8)</u>	<u>\$ 75,864</u>
December 31, 2020					
	Valuation Hierarchy	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		<u>\$ 75,953</u>	<u>\$ 1</u>	<u>\$ —</u>	<u>\$ 75,954</u>

As of March 31, 2021, the remaining contractual maturities for available-for-sale securities were less than one year.

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 March 31, 2021. During the three months ended March 31, 2021 and 2020, the Company did not recognize other-than-temporary impairment losses related to its short-term investments.

5. Balance Sheet Components

Inventories

Inventories consist of the following (in thousands):

	March 31, 2021	December 31, 2020
Raw materials	\$ 10,852	\$ 7,989
Work in process	7,638	6,200
Finished goods	6,064	4,195
Total inventories	<u>\$ 24,554</u>	<u>\$ 18,384</u>

Accrued Expenses and Other Current Liabilities

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

	March 31, 2021	December 31, 2020
Accrued inventory	\$ 3,058	\$ 3,576
Accrued research and development expenses	98	175
Accrued professional services	2,693	2,187
Others	2,334	1,965
Total accrued expenses and other current liabilities	<u>\$ 8,183</u>	<u>\$ 7,903</u>

Accrued Warranty Liability

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

	March 31, 2021	December 31, 2020
Balance at the beginning of the period	\$ 2,913	\$ 1,702
Additions charge to cost of product revenue	1,625	4,858
Consumption	(1,678)	(3,647)
Balance at the end of the period	<u>\$ 2,860</u>	<u>\$ 2,913</u>

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.

Indemnifications

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

7. Term Loan

Term loan consists of the following (in thousands):

	March 31, 2021	December 31, 2020
Principal of term loan	\$ 30,000	\$ 30,000
Unamortized debt discount	(304)	(326)
Total term loan, noncurrent	<u>\$ 29,696</u>	<u>\$ 29,674</u>

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 March 31, 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 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 March 31, 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 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 March 31, 2021, 4,460,000 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 Employee Share Purchase Plan (ESPP) was increased by 427,000 shares as a result of the automatic increase pursuant to the ESPP. As of March 31, 2021, 1,034,000 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 purchase date, whichever is lower. During the three months ended March 31, 2021, 80,000 shares of common stock were issued under the ESPP. No shares of common stock were issued during the three months ended March 31, 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	
	March 31,	
	2021	2020
Cost of revenue	\$ 75	\$ 19
Research and development	1,165	118
Sales and marketing	1,742	82
General and administrative	2,870	361
Total stock-based compensation expense	\$ 5,852	\$ 580

Stock Options with Performance and Market Conditions

As of December 31, 2020, the Company had 1,933,000 shares of 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 March 31, 2021, all outstanding stock options with performance and market-based vesting conditions were fully vested other than 151,000 shares of these stock options that are scheduled to vest in September 2021.

For the three months ended March 31, 2021, the Company recorded stock-based compensation expense of \$4.2 million related to these stock options. No such expense was recognized for the three months ended March 31, 2020 as the performance vesting condition was not satisfied until the closing of the IPO in September 2020. Unamortized stock-based compensation expense related to these awards amounted to \$0.5 million as of March 31, 2021, which the Company expects to recognize over an estimated weighted-average period of 0.3 years.

9. Income Taxes

For the three months ended March 31, 2021 and 2020, the Company incurred an income tax provision of an insignificant amount and zero, respectively. The U.S. federal and state net deferred tax assets have been fully reserved, as the Company believes it is not more likely than not that the benefit will be realized.

10. Net Income (Loss) Per Share Attributable to Common Stockholders

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

	Three Months Ended March 31,	
	2021	2020
Numerator:		
Net loss	\$ (30,025)	\$ (20,650)
Adjustment to redemption value on redeemable convertible preferred stock	—	(362)
Deemed dividend on settlement of accrued dividend	—	42,530
Undistributed earnings allocated to participating securities	—	(18,131)
Net income (loss) attributable to common stockholders, basic	\$ (30,025)	\$ 3,387
Undistributed earnings reallocated to dilutive potential common shares	—	774
Net income (loss) attributable to common stockholders, diluted	<u>\$ (30,025)</u>	<u>\$ 4,161</u>
Denominator:		
Weighted-average shares of common stock, basic	42,760	4,388
Effect of dilutive stock options	—	1,242
Weighted-average shares of common stock, diluted	<u>42,760</u>	<u>5,630</u>
Net income (loss) per share attributable to common stockholders		
Basic	<u>\$ (0.70)</u>	<u>\$ 0.77</u>
Diluted	<u>\$ (0.70)</u>	<u>\$ 0.74</u>

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

	March 31,	
	2021	2020
Stock options to purchase common stock	5,019	2,124
Warrant to purchase common stock	63	—
Restricted stock units	403	—
Shares committed under ESPP	7	—
Redeemable convertible preferred stock, on an as-if converted basis	—	25,958
Warrants to purchase redeemable convertible preferred stock	—	505
Total	<u>5,492</u>	<u>28,587</u>

11. Subsequent Event

On April 13, 2021, the Company completed its follow-on public offering and sold 2,946,000 shares of its 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 \$149.7 million after deducting underwriting discounts and commissions and before expenses.

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 Securities and Exchange Commission (SEC) on March 22, 2021.

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, Tablo frees patients and providers from the burdensome infrastructure required to operate traditional dialysis machines. The integration of water purification and on-demand dialysate production 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 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 preventative maintenance 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 solution through our direct sales organization, which covers most major metropolitan markets in the United States. As of March 31, 2021, our sales organization is comprised of 33 capital sales team members, responsible for generating new customer demand for Tablo, and 57 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 82 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 executing a well-defined, three-pronged strategy designed to expand gross margins. First, we have insourced our console manufacturing to help lower console cost. Second, we are adding a second-source contract manufacturer for our cartridges to gain higher efficiency and lower material cost. Third, 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 \$22.9 million and \$7.2 million for the three months ended March 31, 2021 and 2020, respectively.

For the three months ended March 31, 2021 and 2020, we incurred net losses of \$30.0 million and \$20.7 million, respectively. As of March 31, 2021, we had an accumulated deficit of \$524.1 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 \$149.7 million after deducting underwriting discounts and commissions and before expenses.

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, 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 follow the 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. For employees working on-site, we have and continue to provide personal protective equipment, practice social distancing, enforce mask wearing and increase sanitizing standards, and have also implemented COVID-19 testing at our facilities. We also continue to support remote work arrangements for certain employees. In addition, 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, 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. However, we cannot predict how long the pandemic and measures intended to contain the spread of COVID-19 will continue and what effect COVID-19 and the associated

containment measures will ultimately have 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 months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,	
	2021	2020
Revenue:		
Product revenue	\$ 18,210	\$ 5,926
Service and other revenue	4,706	1,264
Total revenue	22,916	7,190
Cost of revenue:		
Cost of product revenue	20,577	9,562
Cost of service and other revenue	2,050	1,192
Total cost of revenue	22,627	10,754
Gross profit	289	(3,564)
Operating expenses:		
Research and development	7,570	5,838
Sales and marketing	13,149	7,282
General and administrative	9,246	3,526
Total operating expenses	29,965	16,646
Loss from operations	(29,676)	(20,210)
Interest income and other income, net	112	460
Interest expense	(422)	(1,001)
Change in fair value of redeemable convertible preferred stock warrant liability	—	101
Loss before provision for income taxes	(29,986)	(20,650)
Provision for income taxes	39	—
Net loss	\$ (30,025)	\$ (20,650)

Comparison of the Three Months Ended March 31, 2021 and 2020

Revenue

<i>(dollars in thousands)</i>	Three Months Ended March 31,		Change	
	2021	2020	\$	%
Revenue:				
Product revenue	\$ 18,210	\$ 5,926	\$ 12,284	207%
Service and other revenue	4,706	1,264	3,442	272%
Total revenue	\$ 22,916	\$ 7,190	15,726	219%

Product revenue increased by \$12.3 million, or 207% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020 driven by a \$9.7 million increase in consoles revenue and a \$2.6 million increase in consumables revenue. The increase in consoles revenue was driven by new customer adoption, fleet expansion across existing customers, and a \$0.7 million increase in console leasing revenue. The increase in consumables revenue was driven by our growth in console installed base and higher utilization of the installed base.

Service and other revenue increased by \$3.4 million, or 272% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. The increase was primarily due to services associated with our growth in console installed base, including leased consoles.

Cost of Revenue, Gross Profit and Gross Margin

<i>(dollars in thousands)</i>	Three Months Ended March 31,		Change	
	2021	2020	\$	%
Cost of revenue:				
Cost of product revenue	\$ 20,577	\$ 9,562	\$ 11,015	115%
Cost of service and other revenue	2,050	1,192	858	72%
Total cost of revenue	\$ 22,627	\$ 10,754	11,873	110%
Gross profit	289	(3,564)	3,853	108%
Gross margin	1.3 %	(49.6) %		

Cost of product revenue increased by \$11.0 million, or 115% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. This increase was primarily due to higher console and consumable volume of \$15.1 million, higher manufacturing overhead of \$0.5 million and higher depreciation expense for leased consoles of \$0.2 million. This was offset by a \$4.8 million reduction in product costs.

Cost of service and other revenue increased by \$0.9 million, or 72% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. This increase was primarily due to additional headcount costs in our service department, which were offset by higher absorption of these costs across our larger installed base.

Gross profit increased by \$3.9 million, or 108% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. The gross margin percentage improved by 50.9 percentage points for the three months ended March 31, 2021, as compared to the three months ended March 31, 2020, driven primarily by \$7.0 million related to higher margin sales of our products and \$2.6 million in higher service revenue as a result of our larger installed base, including leased consoles. This was offset by \$5.2 million in increased costs as a result of selling more product and a \$0.5 million increase in higher manufacturing overhead.

Operating Expenses

<i>(dollars in thousands)</i>	Three Months Ended March 31,		Change	
	2021	2020	\$	%
Operating expenses:				
Research and development	\$ 7,570	\$ 5,838	\$ 1,732	30%
Sales and marketing	13,149	7,282	5,867	81%
General and administrative	9,246	3,526	5,720	162%
Total operating expenses	\$ 29,965	\$ 16,646	13,319	80%

Research and development expenses increased by \$1.7 million, or 30% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. The increase was primarily due to a \$1.8 million increase in compensation and personnel costs, which includes a \$1.0 million increase in stock-based compensation expense, and a \$0.2 million increase in consultant services. The increases were partially offset by a \$0.3 million decrease in supplies and materials.

Sales and marketing expenses increased by \$5.9 million, or 81% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. The increase was primarily due to a \$4.5 million increase in compensation and personnel costs, which includes a \$1.7 million increase in stock-based compensation expense and a \$1.1 million increase in commission expense, a \$0.9 million increase in clinical sales consultant services, \$0.3 million increase in facilities and other allocated costs and \$0.1 million increase in freight expenses.

General and administrative expenses increased by \$5.7 million, or 162% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020. The increase was primarily due to a \$5.1 million increase in compensation and personnel costs, which includes a \$2.5 million increase in stock-based compensation expense, a \$0.6 million increase in professional and consultant services associated with new public company status and a \$0.4 million increase in depreciation expense. The increases were partially offset by a \$0.4 million decrease in facilities and other allocated costs.

Other Income (Expense), Net

<i>(dollars in thousands)</i>	Three Months Ended March 31,		Change	
	2021	2020	\$	%
Interest income and other income, net	\$ 112	\$ 460	\$ (348)	(76)%
Interest expense	(422)	(1,001)	579	(58)%
Change in fair value of redeemable convertible preferred stock warrant liability	—	101	(101)	*
Total other expense, net	<u>\$ (310)</u>	<u>\$ (440)</u>	130	(30)%

* Not meaningful

Interest income and other income, net decreased by \$0.3 million, or 76% for the three months ended March 31, 2021 as compared to the three months ended March 31, 2020, driven by lower interest rates and a lower average balance in cash, cash equivalents and short-term investment securities in the first quarter of 2021.

Interest expense decreased by \$0.6 million, or 58% for the three months ended March 31, 2021 as compared to the three months ended March 31, 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 shares 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 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.

Liquidity and Capital Resources

Sources of Liquidity

As of March 31, 2021, the Company had cash, cash equivalents and short-term investments of \$277.5 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 \$310.8 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 \$149.7 million, after deducting underwriting discounts and commissions and before expenses (see Note 11 to the condensed financial statements for further details).

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):

	Three Months Ended March 31,	
	2021	2020
Net cash (used in) provided by:		
Operating activities	\$ (38,616)	\$ (24,893)
Investing activities	(6,807)	19,159
Financing activities	2,218	126,770
Net increase in cash, cash equivalents and restricted cash	<u>\$ (43,205)</u>	<u>\$ 121,036</u>

Operating Activities

The net cash used in operating activities of \$38.6 million for the three months ended March 31, 2021 was due to a net loss of \$30.0 million and a net cash outflow from the change in our operating assets and liabilities of \$16.3 million, which were partially offset by adjustments for stock-based compensation expense of \$5.9 million, depreciation and amortization of \$1.2 million, non-cash lease expense of \$0.2 million, non-cash interest expense of \$0.1 million, and provision for inventories of \$0.1 million. The net cash outflow from operating assets and liabilities was primarily due to an increase in inventories of \$7.2 million due to the timing of inventory purchases including advance purchases of inventory due to anticipated demand and to mitigate supply chain disruptions, which partially related to COVID-19, an increase in accounts receivable of \$5.6 million due to timing of collections, a decrease in accrued payroll and related benefits of \$4.2 million mainly due to the payment of 2020 annual cash bonuses to our employees, an increase in prepaid expenses and other assets of \$1.0 million and a decrease in operating lease liabilities of \$0.2 million. The net cash outflow from operating assets and liabilities was partially offset by an increase in account payable and accrued expenses and other current liabilities of \$1.8 million due to timing of vendor payments and an increase in deferred revenue of \$0.3 million due to the growth of our business.

The net cash used in operating activities of \$24.9 million for the three months ended March 31, 2020 was due to a net loss of \$20.7 million and a net cash outflow from the change in our net operating assets and liabilities of \$5.3 million, which were partially offset by adjustments for stock-based compensation expense of \$0.6 million, depreciation and amortization of \$0.3 million and non-cash interest expense of \$0.2 million. The net cash outflow from operating assets and liabilities was primarily due to an increase in accounts receivable of \$3.1 million, a decrease in accrued payroll and related benefits of \$2.7 million mainly due to the payment of 2019 annual cash bonuses to our employees and a decrease in accounts payable of \$1.4 million due to timing of payments. The net cash outflow from operating assets and liabilities was partially offset by a decrease in inventories of \$0.8 million due to higher demand and an increase in deferred revenue of \$0.8 million due to the growth in our business.

Investing Activities

The net cash used in investing activities of \$6.8 million for the three months ended March 31, 2021 was due primarily to the purchases of short-term investments of \$25.8 million and the purchases of property and equipment of \$0.9 million, partially offset by the sales and maturities of short-term investments of \$19.9 million.

The net cash provided by investing activities for the three months ended March 31, 2020 was \$19.2 million and related primarily to the sales and maturities of short-term investments of \$22.0 million, partially offset by the purchases of property and equipment of \$2.8 million.

Financing Activities

The net cash provided by financing activities of \$2.2 million for the three months ended March 31, 2021 was due to the proceeds of \$2.2 million from employee exercises of stock options and employee stock purchase plan purchases.

The net cash provided by financing activities for the three months ended March 31, 2020 was due primarily to the net proceeds of \$126.8 million from the issuance of our Series E redeemable convertible preferred stock.

Contractual Obligations and Commitments

During the three months ended March 31, 2021, there have been no material changes outside the ordinary course of business to our contractual obligations from those disclosed in “*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.

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 most recent Annual Report on Form 10-K filed with the SEC on March 22, 2021. 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.

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 short-term nature of our cash, cash equivalents and short-term investments.

As of March 31, 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, 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 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 the Chief Executive Officer and the Chief Financial Officer, to allow timely decisions regarding required disclosures. Any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objective and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on that evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that our disclosure controls and procedures were effective at a reasonable assurance level as of the 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.

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 Annual Report on Form 10-K for the fiscal year ended December 31, 2020, 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 Annual Report, except as set forth below. The risks described in our Annual Report as updated below are not the only risks that we face. Additional risks and uncertainties not precisely known to us, or that we currently deem to be immaterial, may also arise and materially impact our business. If any of these risks occur, our business, results of operations and financial condition could be materially and adversely affected and the trading price of our common stock could decline.

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 and may continue to use a contract manufacturing partner as a second source for the production of Tablo consoles. 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.

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

(a) Sales of Unregistered Securities

None.

(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.

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	XBRL Instance Document				
101.SCH	XBRL Taxonomy Extension Schema Document				
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document				
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.

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

I, Leslie Trigg, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Outset Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2021

By:

/s/ Leslie Trigg

Leslie Trigg

Chief Executive Officer
(Principal Executive Officer)

**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, Rebecca Chambers, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Outset Medical, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 5, 2021

By:

/s/ Rebecca Chambers

Rebecca Chambers
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 March 31, 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 knowledge:

1. The Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934, as amended; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations the Company.

May 5, 2021

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

May 5, 2021

By: /s/ Rebecca Chambers
Rebecca Chambers
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.