# 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, 2022**

**OR**

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

**For the transition period from ______ to**

**Commission File Number: 001-39513**

# Outset Medical, Inc.
**(Exact Name of Registrant as Specified in its Charter)**

| | |
|---|---|
| **Delaware**<br>**(State or other jurisdiction of incorporation or organization)** | **20-0514392**<br>**(I.R.S. Employer Identification No.)** |
| **3052 Orchard Dr.**<br>**San Jose, California**<br>**(Address of principal executive offices)** | **95134**<br>**(Zip Code)** |

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

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

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

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

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

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

| | | | |
|---|---|---|---|
| Large accelerated filer | ☒ | Accelerated filer | ☐ |
| Non-accelerated filer | ☐ | Smaller reporting company | ☐ |
| Emerging growth company | ☐ | | |

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

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

As of April 22, 2022, the registrant had 47,794,265 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, 2022 (Unaudited) | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 114,346 | $ 182,348 |
| Short-term investments | 187,921 | 157,140 |
| Accounts receivable, net | 26,899 | 25,600 |
| Inventories | 42,873 | 39,185 |
| Prepaid expenses and other current assets | 5,387 | 5,529 |
| Total current assets | 377,426 | 409,802 |
| Restricted cash | 33,311 | 33,311 |
| Property and equipment, net | 13,882 | 12,964 |
| Operating lease right-of-use assets | 6,962 | 7,231 |
| Other assets | 161 | 156 |
| Total assets | $ 431,742 | $ 463,464 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 5,149 | $ 1,763 |
| Accrued compensation and related benefits | 13,478 | 24,948 |
| Accrued expenses and other current liabilities | 18,610 | 13,789 |
| Accrued warranty liability | 3,628 | 3,704 |
| Deferred revenue, current | 6,833 | 6,340 |
| Operating lease liabilities, current | 1,192 | 1,151 |
| Total current liabilities | 48,890 | 51,695 |
| Accrued interest, noncurrent | 840 | 721 |
| Deferred revenue, noncurrent | 194 | 312 |
| Operating lease liabilities, noncurrent | 6,581 | 6,893 |
| Term loan, noncurrent | 29,784 | 29,762 |
| Total liabilities | 86,289 | 89,383 |
| Commitments and contingencies (Note 6) | | |
| Stockholders' equity: | | |
| Preferred stock, $0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of March 31, 2022 and December 31, 2021 | — | — |
| Common stock, $0.001 par value; 300,000 shares authorized as of March 31, 2022 and December 31, 2021; 47,712 and 47,241 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively | 48 | 47 |
| Additional paid-in capital | 1,008,940 | 1,000,212 |
| Accumulated other comprehensive loss | (649) | (184) |
| Accumulated deficit | (662,886) | (625,994) |
| Total stockholders' equity | 345,453 | 374,081 |
| Total liabilities and stockholders' equity | $ 431,742 | $ 463,464 |

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

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

| | Three Months Ended March 31, 2022 | Three Months Ended March 31, 2021 |
|---|---|---|
| Revenue: | | |
| Product revenue | $ 25,664 | $ 18,210 |
| Service and other revenue | 4,886 | 4,706 |
| Total revenue | 30,550 | 22,916 |
| Cost of revenue: | | |
| Cost of product revenue | 23,110 | 20,577 |
| Cost of service and other revenue | 2,998 | 2,050 |
| Total cost of revenue | 26,108 | 22,627 |
| Gross profit | 4,442 | 289 |
| Operating expenses: | | |
| Research and development | 10,831 | 7,570 |
| Sales and marketing | 20,377 | 13,149 |
| General and administrative | 9,709 | 9,246 |
| Total operating expenses | 40,917 | 29,965 |
| Loss from operations | (36,475) | (29,676) |
| Interest income and other income, net | 120 | 112 |
| Interest expense | (422) | (422) |
| Loss before provision for income taxes | (36,777) | (29,986) |
| Provision for income taxes | 115 | 39 |
| Net loss | $ (36,892) | $ (30,025) |
| Net loss per share, basic and diluted | $ (0.78) | $ (0.70) |
| Shares used in computing net loss per share, basic and diluted | 47,487 | 42,760 |

*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, | |
|---|---|---|
| | **2022** | **2021** |
| Net loss | $ (36,892) | $ (30,025) |
| Other comprehensive loss: | | |
| Unrealized loss on available-for-sale securities | (465) | (9) |
| Comprehensive loss | $ (37,357) | $ (30,034) |

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

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

| | Common Stock | | Additional Paid-in Capital | Accumulated Other Comprehensive Income (Loss) | Accumulated Deficit | Total Stockholders Equity |
|---|---|---|---|---|---|---|
| | Shares | Amount | | | | |
| **Balance as of December 31, 2021** | 47,241 | $ 47 | $ 1,000,212 | $ (184) | $ (625,994) | $ 374,081 |
| Issuance of common stock through employee stock purchase plan | 55 | — | 2,063 | — | — | 2,063 |
| Issuance of common stock for settlement of RSUs | 88 | — | — | — | — | — |
| Stock option exercises | 328 | 1 | 1,659 | — | — | 1,660 |
| Stock-based compensation expense | — | — | 5,006 | — | — | 5,006 |
| Unrealized loss on available-for-sale securities | — | — | — | (465) | — | (465) |
| Net loss | — | — | — | — | (36,892) | (36,892) |
| **Balance as of March 31, 2022** | 47,712 | $ 48 | $ 1,008,940 | $ (649) | $ (662,886) | $ 345,453 |

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

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

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

*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, 2022 | Three Months Ended March 31, 2021 |
|---|---|---|
| **Cash flows from operating activities:** | | |
| Net loss | $ (36,892) | $ (30,025) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Stock-based compensation expense | 5,006 | 5,852 |
| Depreciation and amortization | 1,262 | 1,246 |
| Non-cash lease expense | 269 | 249 |
| Non-cash interest expense | 140 | 140 |
| Accretion of discount on investments, net | 667 | 60 |
| Provision for inventories | 496 | 115 |
| Other non-cash items | 3 | 5 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | (1,299) | (5,646) |
| Inventories | (4,184) | (7,247) |
| Prepaid expenses and other assets | 137 | (981) |
| Accounts payable | 3,276 | 1,613 |
| Accrued payroll and related benefits | (11,470) | (4,244) |
| Accrued expenses and other current liabilities | 4,226 | 164 |
| Accrued warranty liability | (76) | (53) |
| Deferred revenue | 375 | 305 |
| Operating lease liabilities | (271) | (169) |
| Net cash used in operating activities | (38,335) | (38,616) |
| **Cash flows from investing activities:** | | |
| Purchases of property and equipment | (1,478) | (919) |
| Purchases of investment securities | (64,712) | (25,788) |
| Sales and maturities of investment securities | 32,800 | 19,900 |
| Net cash used in investing activities | (33,390) | (6,807) |
| **Cash flows from financing activities:** | | |
| Proceeds from stock option exercises and employee stock purchase plan purchases | 3,723 | 2,218 |
| Net cash provided by financing activities | 3,723 | 2,218 |
| Net decrease in cash, cash equivalents and restricted cash | (68,002) | (43,205) |
| Cash, cash equivalents and restricted cash as of beginning of period | 215,659 | 328,283 |
| Cash, cash equivalents and restricted cash as of end of period | $ 147,657 | $ 285,078 |
| | | |
| **Supplemental cash flow disclosures:** | | |
| Cash paid for income taxes | $ 205 | $ — |
| Cash paid for interest | $ 282 | $ 282 |
| Cash paid for amounts included in the measurement of operating lease liabilities | $ 271 | $ 169 |
| **Supplemental non-cash investing and financing activities:** | | |
| Capital expenditures included in accounts payable and accrued expenses | $ 907 | $ 238 |
| Transfer of inventories to property and equipment | $ — | $ 962 |

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

## 1. Description of Business

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

### *Liquidity*

Since inception, the Company has incurred net losses and negative cash flows from operations. During the three months ended March 31, 2022 and 2021, the Company incurred a net loss of $36.9 million and $30.0 million, respectively. As of March 31, 2022, the Company had an accumulated deficit of $662.9 million.

As of March 31, 2022, the Company had cash, cash equivalents and short-term investments of $302.3 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 $335.6 million. Management expects to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term while the Company makes investments to support its anticipated growth. Management believes that the Company's existing cash, cash equivalents, short-term investments and cash generated from sales, will be sufficient to meet its anticipated needs for at least the next 12 months from the issuance date of the accompanying condensed financial statements.

### *Basis of Presentation*

The accompanying condensed financial statements are unaudited and have been prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) and on the same basis as the annual financial statements and, in the opinion of management, reflect all adjustments, which include only normal recurring adjustments, that are necessary for the fair statement of the Company's financial position, results of operations, comprehensive loss, and cash flows for the interim periods presented. The financial data and the other financial information disclosed in these notes to the condensed financial statements related to the three-month period are also unaudited. The results of operations for the three months ended March 31, 2022 are not necessarily indicative of the results of operations to be anticipated for any other future annual or interim period. The condensed balance sheet as of December 31, 2021 included herein was derived from the audited financial statements as of that date.

These unaudited condensed financial statements should be read in conjunction with the Company's audited financial statements and related notes for the year ended December 31, 2021, which are included in the Annual Report on Form 10-K for the fiscal year ended December 31, 2021 filed with the Securities and Exchange Commission (SEC) on February 23, 2022 (2021 Annual Report).

All share amounts disclosed in the notes to the condensed financial statements are rounded to the nearest thousand except for per share data.

## 2. Summary of Significant Accounting Policies

During the three months ended March 31, 2022, there have been no material changes to the Company's significant accounting policies as described in its 2021 Annual Report that have had a material impact on the Company's condensed financial statements and related notes.

***Recently Issued Accounting Pronouncements Not Yet Adopted***

In June 2016, the Financial Accounting Standards Board (FASB) issued ASU No. 2016-13, *Financial Instruments - Credit Losses (Topic 326) Measurement of Credit Losses on Financial Instruments* (ASU 2016-13), which requires an entity to utilize a new impairment model known as the current expected credit loss (CECL) model to estimate its lifetime "expected credit loss" and record an allowance that, when deducted from the amortized cost basis of the financial assets and certain other instruments, including but not limited to available-for-sale debt securities. Credit losses relating to available-for-sale debt securities will be recorded through an allowance for credit losses rather than as a direct write-down to the security. ASU 2016-13 requires a cumulative effect adjustment to the balance sheet as of the beginning of the first reporting period in which the guidance is effective. In November 2019, the FASB issued ASU 2019-10, *Financial Instruments—Credit Losses (Topic 326), Derivatives and Hedging (Topic 815) and Leases (Topic 842): Effective Dates*, which defers the effective date of ASU 2016-13 to fiscal years beginning after December 15, 2022 for all entities except SEC reporting companies that are not smaller reporting companies. ASU 2016-13 will be effective for the Company beginning January 1, 2023. The Company is currently evaluating the impact of the adoption of ASU 2016-13 on its financial statements.

**3. Revenue and Deferred Revenue**

***Disaggregation of Revenue***

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

| | Three Months Ended March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Consoles | $ 18,051 | $ 14,766 |
| Consumables | 7,613 | 3,444 |
| Total product revenue | 25,664 | 18,210 |
| Service and other revenue | 4,886 | 4,706 |
| Total revenue | $ 30,550 | $ 22,916 |

For the three months ended March 31, 2022, $0.7 million of consoles revenue was from console operating lease arrangements, compared to $1.3 million for the three months ended March 31, 2021.

***Remaining Performance Obligations and Contract Liabilities***

As of March 31, 2022, the aggregate amount of the transaction price allocated to the remaining performance obligations related to customer service contracts that are unsatisfied or partially unsatisfied was $7.0 million, which is recorded as deferred revenue on the Company's condensed balance sheets. Of that amount, $6.8 million will be recognized as revenue during the next 12 months and $0.2 million thereafter.

The contract liabilities consist of deferred revenue which represents payments received in advance of revenue recognition. Revenue under these agreements is recognized over the related service period. During the three months ended March 31, 2022, the Company recognized $2.5 million of previously deferred revenue.

## 4. Fair Value Measurements

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

| | Valuation Hierarchy | March 31, 2022 Amortized Costs | Gross Unrealized Holding Gains | Gross Unrealized Holding Losses | Aggregate Fair Value |
|---|---|---|---|---|---|
| **Assets:** | | | | | |
| Cash equivalents: | | | | | |
| Money market funds | Level 1 | $ 32,747 | $ — | $ — | $ 32,747 |
| Short-term investments: | | | | | |
| U.S. Treasury securities | Level 1 | 68,129 | 2 | (275) | 67,856 |
| Corporate debt | Level 2 | 109,752 | 2 | (378) | 109,376 |
| Commercial paper | Level 2 | 10,689 | — | — | 10,689 |
| Total cash equivalents and short-term investments | | $ 221,317 | $ 4 | $ (653) | $ 220,668 |

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

As of March 31, 2022, the remaining contractual maturities for available-for-sale securities were between one month to twelve months.

Impairment assessments are made at the individual security level at each reporting period. When the fair value of an available-for-sale security is less than its cost at the balance sheet date, a determination is made as to whether the impairment is other-than-temporary and, if it is other-than-temporary, an impairment loss is recognized in earnings equal to the difference between the investment's amortized cost and fair value at such date. There were no unrealized losses for securities in an unrealized loss position for more than 12 months as of March 31, 2022. During the three months ended March 31, 2022 and 2021, the Company did not recognize other-than-temporary impairment losses related to its investment securities.

## 5. Balance Sheet Components

### *Cash, Cash Equivalents and Restricted Cash*

As of March 31, 2022 and December 31, 2021, the restricted cash balance of $33.3 million primarily relates to contractual obligations under the SVB Loan and Security Agreement (see Note 7) and collateral for building leases in San Jose, CA and Tijuana Mexico.

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

| | March 31, 2022 | March 31, 2021 |
|---|---|---|
| Cash and cash equivalents | $ 114,346 | $ 251,767 |
| Restricted cash | 33,311 | 33,311 |
| Total cash, cash equivalents and restricted cash | $ 147,657 | $ 285,078 |

***Inventories***

Inventories consist of the following (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Raw materials | $ 15,970 | $ 18,114 |
| Work in process | 9,501 | 6,054 |
| Finished goods | 17,402 | 15,017 |
| Total inventories | $ 42,873 | $ 39,185 |

***Accrued Expenses and Other Current Liabilities***

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

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Accrued inventory | $ 6,730 | $ 4,808 |
| Accrued research and development expenses | 802 | 574 |
| Accrued professional services | 1,510 | 1,269 |
| Accrued rebate | 3,449 | 3,121 |
| Other | 6,119 | 4,017 |
| Total accrued expenses and other current liabilities | $ 18,610 | $ 13,789 |

**6. Commitments and Contingencies**

***Litigation***

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

***Indemnification***

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

**7. Term Loan**

Term loan consists of the following (in thousands):

| | March 31, 2022 | December 31, 2021 |
|---|---|---|
| Principal of term loan | $ 30,000 | $ 30,000 |
| Unamortized debt discount | (216) | (238) |
| Total term loan, noncurrent | $ 29,784 | $ 29,762 |

***SVB Loan and Security Agreement***

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

The SVB Term Loan matures on November 1, 2025. Payments under the SVB Term Loan are for interest only through May 2023, and then 30 monthly principal and interest payments from June 2023 until maturity. The SVB Term Loan bears interest at the greater of (A) 0.5% above the Prime Rate as reported in the Wall Street Journal and (B) 3.75% (4.00% as of March 31, 2022). The Company is obligated to maintain a restricted cash balance greater or equal to the outstanding principal balance of $30.0 million of the SVB Term Loan.

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

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

Debt issuance costs paid directly to SVB and other debt issuance costs amounting to $0.4 million were accounted for as discounts on the SVB Term Loan. These debt discounts, along with the final payment fee, are being amortized over the term of the SVB Term Loan using the effective interest rate method.

## 8. Equity Incentive Plan

***Equity Incentive Plans***

On January 1, 2022, the number of shares of common stock reserved for the issuance of awards under the Company’s 2020 Equity Incentive Plan (the 2020 Plan) was increased by 1,890,000 shares as a result of the automatic increase pursuant to the 2020 Plan. As of March 31, 2022, 5,524,000 shares were reserved for future issuance under the 2020 Plan.

***Employees Share Purchase Plan (ESPP)***

On January 1, 2022, the number of shares of common stock reserved for purchase under the Company’s ESPP was increased by 472,000 shares as a result of the automatic increase pursuant to the ESPP. As of March 31, 2022, 1,416,000 shares of common stock were reserved for issuance in connection with the current and future offering periods under the ESPP.

***Restricted Stock***

The Company issues restricted stock units (RSUs) and performance stock units (PSUs), both of which are considered restricted stock. The Company grants restricted stock pursuant to the 2020 Plan and satisfies such grants through the issuance of new shares. RSUs are share awards that, upon vesting, will deliver to the holder shares of our common stock.

RSUs with a service-based vesting condition granted to a grantee, beginning in February 2022, generally vest over a three year period as follows either: (i) 25% on the first anniversary of the original vesting date, 25% quarterly over the course of the second year, and 50% quarterly over the course of the third year, or (ii) 33% on the first anniversary of the original vesting date, with the balance vesting quarterly over the remaining two years. Prior to February 2022, RSUs with a service-based vesting condition granted to a grantee generally vest at a rate of 25% on the first anniversary of the original vesting date, with the balance vesting quarterly over the remaining three years.

In 2022, the Company issued a mix of 50% PSUs and 50% RSUs to its CEO, and a mix of 20% PSUs and 80% RSUs to its other executive officers and certain other senior leaders. These PSUs are earned and vest over performance and vesting periods extending through 2024 based on achievement against two metrics: (1) an operational metric tied to the number of patients treating at home on Tablo as of the end of 2023, with 50% of earned units vesting after certification of the achievement level following the end of 2023 and the remaining 50% of earned units vesting at the end of 2024 (performance-based vesting conditions, referred to as the Home PSUs) and (2) the Company's relative total stockholder return (relative TSR) over a two-year performance period as compared to companies in a pre-determined index of medical device companies, with 100% of earned units vesting at the end of 2024 (market-based vesting conditions, referred to as the Relative TSR PSUs).

The 2023 target for the Home PSUs is expected to be determined and approved by the Compensation Committee in late 2022 or early 2023. Given such target has not yet been established, the grant date for these Home PSUs will only be established when the Compensation Committee approves and the Company communicates the target to the award recipients, which will then trigger the service inception date, the fair value of the awards, and the associated expense recognition period. Therefore, no expense is expected to be recognized for these Home PSUs until the grant date is established.

***Stock-Based Compensation Expense***

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Cost of revenue | $ 93 | $ 75 |
| Research and development | 1,158 | 1,165 |
| Sales and marketing | 1,706 | 1,742 |
| General and administrative | 2,049 | 2,870 |
| Total stock-based compensation expense | $ 5,006 | $ 5,852 |

## 9. Income Taxes

For each of the three months ended March 31, 2022 and 2021, the Company incurred an income tax provision of an insignificant amount, which related to foreign income taxes. The U.S. federal and state net deferred tax assets have been fully offset by a valuation allowance, as the Company believes it is not more likely than not that the deferred tax assets will be realized.

## 10. Net Loss Per Share

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

| | Three Months Ended March 31, | |
|---|---|---|
| | 2022 | 2021 |
| Stock options to purchase common stock | 3,162 | 5,019 |
| Restricted stock units | 1,390 | 403 |
| Performance stock units | 74 | — |
| Shares committed under ESPP | 43 | 7 |
| Warrant to purchase common stock | 63 | 63 |
| Total | 4,732 | 5,492 |

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

*The following discussion of our financial condition and results of operations should be read together with our unaudited condensed financial statements and related notes and other financial information included elsewhere in this Quarterly Report, as well as our audited financial statements and notes thereto and the related Management's Discussion and Analysis of Financial Condition and Results of Operations included in our 2021 Annual Report. As used in this Quarterly Report, references to the "Company," "we," "us," "our," or similar terms refer to Outset Medical, Inc.*

*In addition to historical financial information, this discussion and other parts of this report contain forward-looking statements within the meaning of the federal securities laws. All statements other than statements of historical fact contained in this Quarterly Report are forward-looking statements. The forward-looking statements in this report are only predictions and are based largely on our current expectations and projections about future events and financial trends that we believe may affect our business, financial condition and results of operations. These forward-looking statements are subject to a number of known and unknown risks, uncertainties and assumptions that may cause our actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. Such risks and uncertainties include those described throughout this Quarterly Report, including in this discussion as well as in the section titled "Risk Factors" under Part II, Item 1A below. The forward-looking statements in this Quarterly Report are based upon information available to us as of the date of this Quarterly Report, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements, like all statements in this report, speak only as of their date, and, except as required by law we undertake no obligation to update or revise these statements, whether as a result of any new information, future developments or otherwise. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements.*

### Overview

Our technology is designed to elevate the dialysis experience for patients and help providers overcome traditional care delivery challenges. Requiring only an electrical outlet and tap water to operate, the Tablo® Hemodialysis System frees patients and providers from the burdensome infrastructure required to operate traditional dialysis machines. The integration of water purification and on-demand dialysate production in a single 35-inch compact console enables Tablo to serve as a dialysis clinic on wheels. With a simple-to-use touchscreen interface, two-way wireless data transmission and a proprietary data analytics platform, Tablo is a new holistic approach to dialysis care. Unlike existing hemodialysis machines, which have limited clinical versatility across care settings, Tablo can be used seamlessly across multiple care settings and a wide range of clinical applications.

Tablo leverages cloud technology, making it possible for providers to monitor devices and treatments remotely, perform patient and population analytics, and automate clinical recordkeeping, while also enabling us to release features and enhancements through over-the-air (OTA) updates. Tablo's connectedness also allows it to continually stream more than 500,000 device performance data points after every treatment. We use this data, in conjunction with our diagnostic and predictive algorithms, to determine failure types and, in some instances, predict failures before they occur. In effect, this contributes to a reduction in service hours and an increase in device uptime.

We have generated meaningful evidence to demonstrate that providers can realize significant operational efficiencies, including reducing the cost of their dialysis programs by up to 80% in the intensive care unit. In addition, Tablo has been shown to deliver robust clinical care. In studies we have conducted, patients have reported experiencing fewer symptoms and better quality sleep while on Tablo. We believe Tablo empowers patients, who have traditionally been passive recipients of care, to regain agency and ownership of their treatment. Tablo is cleared by the FDA for use in the hospital, clinic, or home setting.

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.

Tablo is also well suited for home-based dialysis. Our ability to reduce training time, patient dropout, and the supplies and infrastructure required to deliver dialysis in the home can drive efficiency and economic improvements to the home care model. In our home investigational device exemption (IDE) trial, patients reported specific quality of life improvements compared to their experience on the incumbent home dialysis machine. To penetrate this market successfully, we continue to focus on refining our home distribution, logistics and support systems to help ensure they are ready for rapid scale. We are also working with providers, patients, and payors to increase awareness and adoption of transitional care units (TCUs) as a bridge to home-based therapy. To demonstrate the cost advantages of Tablo in the home setting, we are continuing to collect additional patient clinical experience and outcomes data.

We sell our solutions through our direct sales organization, which covers most major metropolitan markets in the United States. As of March 31, 2022, our sales organization is comprised of 38 capital sales team members, responsible for generating new customer demand for Tablo, and 96 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 108 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 generate revenue primarily from the initial sale of Tablo consoles, and recurring sales of per-treatment consumables, including the Tablo cartridge, which generates significant total revenue over the life of the console. We generate additional recurring revenue via annual service contracts and revenue from shipping and handling charged to customers. Our total revenue was $30.6 million and $22.9 million for the three months ended March 31, 2022 and 2021, respectively.

Historically, we have financed our operations and capital expenditures primarily through sales of redeemable convertible preferred stock and common stock, revenue from sales, and debt financing. Since our inception, we have incurred net losses in each year. For the three months ended March 31, 2022 and 2021, we incurred net losses of $36.9 million and $30.0 million, respectively. As of March 31, 2022, we had an accumulated deficit of $662.9 million. We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term.

## Key Factors Affecting Our Performance

We believe that our financial performance has been and in the foreseeable future will continue to be primarily driven by the following factors. While we believe each of these factors presents significant opportunities for our business, they also pose important challenges that we must successfully address in order to sustain our growth and improve our results of operations. Our ability to successfully address the factors below is subject to various risks and uncertainties, including those described in the section titled “Risk Factors.”

### *Market Acceptance of Tablo in Acute Setting*

We plan to further broaden our installed base by continuing to target national and regional Integrated Delivery Networks (IDNs) and health systems, sub-acute long-term acute care hospitals (LTACHs) and skilled nursing facilities (SNFs). In addition, we focus on driving utilization and fleet expansion with existing customers by providing an exceptional user experience delivered through our commercial team and a steady release of software enhancements that amplify Tablo’s operational reliability and clinical versatility. Our ability to successfully execute on this strategy, and thereby increase our revenue, will in part drive our results of operations and the growth of our business.

### *Expansion of Tablo within the Home Setting*

We believe a significant growth opportunity exists within the home hemodialysis market. We are partnering with innovative dialysis clinic providers and health systems who are motivated to grow their home hemodialysis population, and who share our vision of creating a seamless and supported transition to the home. We are also investing in market development over the longer term to expand the home hemodialysis market itself. The expansion of the home hemodialysis market and our ability to penetrate this market will be an important factor in driving the future growth of our business.

### *Gross Margin*

We are continuing to execute a well-defined strategy designed to expand gross margins. First, in the first quarter of 2021, we successfully began production at our own console manufacturing facility in Tijuana, Mexico which we operate in collaboration with our outsourced business administration service provider, TACNA. Second, following our receipt of 510(k) clearance from the FDA for the new cartridge sterilization method in the fourth quarter of 2021, we have qualified a second source to increase Tablo cartridge production through a new manufacturing partner in Mexico, which we anticipate will result in cost reductions, including lower freight costs. Third, we will continue to drive scale across our console platform to leverage our supply base and help improve our manufacturing efficiency. Fourth, we will continue to utilize our cloud-based data system, as well as enhanced product performance, to help drive down the cost of service. Our ability to grow our business will depend in part on these and other measures to control the costs of our products being successful. Likewise, it will be important that we effectively manage the costs of generating our service revenue.

**Impacts of the COVID-19 pandemic**

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

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

Moreover, healthcare providers (including our existing and prospective customers) are facing a nationwide shortage of qualified nurses and other clinical personnel due to long-term trends that have been exacerbated by the COVID-19 pandemic. As competition for these healthcare professionals has intensified, providers are facing increased difficulties attracting and retaining skilled clinical personnel, resulting in increased costs, staffing shortages and other disruptions. These challenging labor market conditions in the healthcare industry have been heightened by the increased demand for, and demand upon, nurses and other staff resulting from the ongoing pandemic. We believe Tablo offers automation and ease-of-use benefits over traditional machines that can enhance our existing and potential customers' ability to support their patient populations despite staffing shortages. However, there is also a risk that the increased costs and other disruptions caused by the shortage of dialysis nurses, technicians and other staff could cause existing or prospective customers to delay continued investment in or adoption of new technologies and postpone purchasing decisions. If our customers continue to face prolonged volatility, uncertainty, and staffing shortages, whether due to the pandemic or otherwise, it could ultimately adversely impact our ability to expand existing customer relationships or attract new customers of Tablo, and have a material adverse effect on our revenues, results of operations, and future growth.

How long the pandemic, and measures intended to contain the spread of COVID-19, will continue remains uncertain and depends on ongoing developments, including but not limited to any resurgences of the virus including emerging variant strains, federal, state, and local government actions taken in response, and continued availability, effectiveness and public acceptance of COVID-19 vaccines. Additionally, the duration and severity of disruptions in the global supply chain, and depend on various factors, including the effectiveness of recent government actions intended to mitigate these disruptions. As a result, we cannot predict what effect COVID-19, the associated containment measures, and the related supply chain disruptions will ultimately have on our business and results of operations, on our customers, or on our suppliers and vendors, in particular for any of our suppliers and vendors that may not qualify as essential businesses and suffer more significant or lengthier disruptions to their business operations. There is no assurance that we will not experience more significant disruptions in our supply chain in the future, particularly if the operations of our contract manufacturing partners, our critical single-source component providers, or the facility we operate in Tijuana, Mexico in collaboration with TACNA, are more severely impacted by the pandemic and associated containment measures.

**Results of Operations**

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021 (in thousands):

| | Three Months Ended March 31, 2022 | Three Months Ended March 31, 2021 |
|---|---|---|
| Revenue: | | |
| Product revenue | $ 25,664 | $ 18,210 |
| Service and other revenue | 4,886 | 4,706 |
| Total revenue | 30,550 | 22,916 |
| Cost of revenue: | | |
| Cost of product revenue | 23,110 | 20,577 |
| Cost of service and other revenue | 2,998 | 2,050 |
| Total cost of revenue | 26,108 | 22,627 |
| Gross profit | 4,442 | 289 |
| Operating expenses: | | |
| Research and development | 10,831 | 7,570 |
| Sales and marketing | 20,377 | 13,149 |
| General and administrative | 9,709 | 9,246 |
| Total operating expenses | 40,917 | 29,965 |
| Loss from operations | (36,475) | (29,676) |
| Interest income and other income, net | 120 | 112 |
| Interest expense | (422) | (422) |
| Loss before provision for income taxes | (36,777) | (29,986) |
| Provision for income taxes | 115 | 39 |
| Net loss | $ (36,892) | $ (30,025) |

***Comparison of the Three Months Ended March 31, 2022 and 2021***

***Revenue***

| *(dollars in thousands)* | Three Months Ended March 31, 2022 | Three Months Ended March 31, 2021 | Change $ | Change % |
|---|---|---|---|---|
| Revenue: | | | | |
| Product revenue | $ 25,664 | $ 18,210 | $ 7,454 | 41 % |
| Service and other revenue | 4,886 | 4,706 | 180 | 4 % |
| Total revenue | $ 30,550 | $ 22,916 | 7,634 | 33 % |

Product revenue increased by $7.5 million, or 41% for the three months ended March 31, 2022 as compared to the same quarter in prior year, driven by a $3.3 million increase in consoles revenue and a $4.2 million increase in consumables revenue. The increase in consoles revenue was driven by new customer adoption and fleet expansion across existing customer sites, which was slightly offset by a $0.6 million decrease in console leasing revenue. The increase in consumables revenue was driven by the growth in our console installed base and higher average selling prices.

Service and other revenue increased by $0.2 million, or 4%, for the three months ended March 31, 2022 as compared to the same quarter in prior year. The increase was primarily due to services associated with the growth in our console installed base, which was offset by a $1.5 million decrease in service revenue from leased consoles.

***Cost of Revenue, Gross Profit and Gross Margin***

| *(dollars in thousands)* | Three Months Ended March 31, 2022 | Three Months Ended March 31, 2021 | Change $ | Change % |
|---|---|---|---|---|
| Cost of revenue: | | | | |
| Cost of product revenue | $ 23,110 | $ 20,577 | $ 2,533 | 12 % |
| Cost of service and other revenue | 2,998 | 2,050 | 948 | 46 % |
| Total cost of revenue | $ 26,108 | $ 22,627 | 3,481 | 15 % |
| Gross profit | 4,442 | 289 | 4,153 | (1,437 )% |
| Gross margin | *14.5* % | *1.3* % | | |

The total cost of revenue increased by $3.5 million, or 15% for the three months ended March 31, 2022 as compared to the same quarter in prior year. This increase was primarily due to growth in sales volume. Gross profit increased by $4.2 million, or 1,437% for the three months ended March 31, 2022 as compared to the same quarter in prior year. The gross margin percentage improved by 13.2 percentage points for the three months ended March 31, 2022, as compared to the same quarter in prior year. This improvement in gross profit and gross margin was primarily driven by the impact of our cost reduction activities. Such improvement was partially offset by the lower service and other gross margin due to expiration of certain lease agreement.

***Operating Expenses***

| | Three Months Ended March 31, | | Change | |
|---|---|---|---|---|
| *(dollars in thousands)* | 2022 | 2021 | $ | % |
| Operating expenses: | | | | |
| Research and development | $ 10,831 | $ 7,570 | $ 3,261 | 43% |
| Sales and marketing | 20,377 | 13,149 | 7,228 | 55% |
| General and administrative | 9,709 | 9,246 | 463 | 5% |
| Total operating expenses | $ 40,917 | $ 29,965 | 10,952 | 37% |

Research and development expenses increased by $3.3 million, or 43% for the three months ended March 31, 2022 as compared to the same quarter in prior year. The increase was primarily due to higher headcount and higher consulting services to support our product development activities. In addition, there was increased infrastructure costs to support our growth.

Sales and marketing expenses increased by $7.2 million, or 55% for the three months ended March 31, 2022 as compared to the same quarter in prior year. The increase was primarily driven by higher headcount, higher commissions due to higher sales, and increased infrastructure costs to support our growth. In addition, there were higher travel and freight expenses for the three months ended March 31, 2022, as compared with the same quarter in prior year. This increase was partially offset by lower clinical sales consultant services expense as we have increased our headcount to insource the services.

General and administrative expenses increased by $0.5 million or 5% for the three months ended March 31, 2022 as compared to the same quarter in prior year. The increase was primarily driven by higher headcount and increased infrastructure costs to support our growth. In addition, there were higher travel and insurance expenses for the three months ended March 31, 2022, as compared with the same quarter in prior year. The increase was partially offset by a decrease in stock-based compensation expense due to the expense related to stock options with performance and market-based vesting conditions in 2020, which was fully recognized as of the end of third quarter of 2021.

***Other Income (Expense), Net***

| | Three Months Ended March 31, | | Change | |
|---|---|---|---|---|
| *(dollars in thousands)* | 2022 | 2021 | $ | % |
| Other income (expenses), net: | | | | |
| Interest income and other income, net | $ 120 | $ 112 | $ 8 | 7% |
| Interest expense | (422) | (422) | — | * |
| Total other expenses, net | $ (302) | $ (310) | 8 | (3)% |

** Not meaningful*

Interest income and other income, net and interest expense for the three months ended March 31, 2022 was relatively consistent with the prior year amount.

## Liquidity and Capital Resources

***Sources of Liquidity***

As of March 31, 2022, we had cash, cash equivalents and short-term investments of $302.3 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 $335.6 million.

Since our inception, we have incurred net losses and negative cash flows from operations. To date, we have financed our operations and capital expenditures primarily through sales of redeemable convertible preferred stock and common stock, revenue from sales, debt financings, and proceeds from stock option exercises and employee stock purchases.

We expect to continue to incur significant expenses for the foreseeable future and to incur operating losses in the near term while we make investments to support our anticipated growth. We may raise additional capital through the issuance of additional equity financing, debt financings, including through refinancing our existing debt, or other sources. If this financing is not available to us at adequate levels or on acceptable terms, we may need to reevaluate our operating plans. If we do raise additional capital through public or private equity offerings, the ownership interest of our existing stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect our existing stockholders' rights. If we raise additional capital through debt financing, we may be subject to covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. We believe that our existing cash, cash equivalents and short-term investments, and cash generated from sales of our products and services, will be sufficient to meet our anticipated needs for at least the next 12 months from the 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, | |
|---|---|---|
| | **2022** | **2021** |
| Net cash (used in) provided by: | | |
| Operating activities | $ (38,335) | $ (38,616) |
| Investing activities | (33,390) | (6,807) |
| Financing activities | 3,723 | 2,218 |
| Net decrease in cash, cash equivalents and restricted cash | $ (68,002) | $ (43,205) |

***Operating Activities***

The net cash used in operating activities of $38.3 million for the three months ended March 31, 2022 was due to a net loss of $36.9 million and a net cash outflow from the change in our operating assets and liabilities of $9.3 million, which were partially offset by adjustments for stock-based compensation expense of $5.0 million, depreciation and amortization of $1.3 million, accretion of discount on investments of $0.7 million, provision for inventories of $0.5 million, non-cash lease expense of $0.3 million, and non-cash interest expense of $0.1 million. The net cash outflow from operating assets and liabilities was primarily due to a decrease in accrued payroll and related benefits mainly due to the payment of 2021 annual cash bonuses to our employees, an increase in inventories due to the timing of inventory purchases including advance purchases of inventory due to anticipated demand and to mitigate supply chain disruptions, an increase in accounts receivable due to timing of collections, and a decrease in operating lease liabilities. The net cash outflow from operating assets and liabilities was partially offset by an increase in accounts payable and accrued expenses and other current liabilities due to timing of vendor payments, an increase in deferred revenue due to the growth of our business, and a decrease in prepaid expenses and other assets.

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 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 due to timing of collections, a decrease in accrued payroll and related benefits mainly due to the payment of 2020 annual cash bonuses to our employees, an increase in prepaid expenses and other assets and a decrease in operating lease liabilities. The net cash outflow from operating assets and liabilities was partially offset by an increase in accounts payable and accrued expenses and other current liabilities due to timing of vendor payments and an increase in deferred revenue due to the growth of our business.

***Investing Activities***

The net cash used in investing activities of $33.4 million for the three months ended March 31, 2022 was due primarily to the purchases of investment securities of $64.7 million and the purchases of property and equipment of $1.5 million, partially offset by the sales and maturities of investment securities of $32.8 million.

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.

*Financing Activities*

The net cash provided by financing activities of $3.7 million for the three months ended March 31, 2022 was due to proceeds of $3.7 million from employee exercises of stock options and ESPP purchases.

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

**Contractual Obligations and Commitments**

During the three months ended March 31, 2022, there have been no material changes to our contractual obligations from those disclosed in "*Management's Discussion and Analysis of Financial Condition and Results of Operations*" included in our 2021 Annual Report.

**Off-Balance Sheet Arrangements**

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

**Critical Accounting Policies and Estimates**

Management's discussion and analysis of the financial condition and results of operations is based on the financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported revenues and expenses incurred during the reporting periods. The estimates are based on historical experience and on various other factors that are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

There have been no significant changes in our critical accounting policies and estimates as compared to the critical accounting policies and estimates disclosed in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our 2021 Annual Report. For additional information, please refer to Note 2 to our unaudited condensed financial statements in this Quarterly Report.

**Recent Accounting Pronouncements**

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

## Item 3. Quantitative and Qualitative Disclosures About Market Risk

There has been no material change in the nature of the Company's interest rate risks or foreign currency exchange risks from those described in Part II Item 7A of our 2021 Annual Report for the year ended December 31, 2021.

## Item 4. Controls and Procedures.

### *Evaluation of Disclosure Controls and Procedures*

Our management, with the participation and supervision of our Chief Executive Officer and Chief Financial Officer, have evaluated the effectiveness of the design and operation of our disclosure controls and procedures pursuant to Rule 13a-15(e) and 15d-15(e) under the Exchange Act as of the end of the period covered by this Quarterly Report. Our disclosure controls and procedures are designed to ensure that information required to be disclosed in the reports we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures are also designed to provide reasonable assurance that such information is accumulated and communicated to our management, including 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.

## PART II—OTHER INFORMATION

### Item 1. Legal Proceedings.

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

### Item 1A. Risk Factors.

You should carefully consider the risk factors discussed in Part I, "Item 1A. Risk Factors" in our 2021 Annual Report, which could materially affect our business, financial position, or future results of operations. There have been no material changes to the risk factors described in our 2021 Annual Report, except as set forth below. The risks described in our 2021 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.

***General economic and financial market conditions may exacerbate our business risks.***

Global macroeconomic conditions and the world's financial markets remain susceptible to significant stresses, including global geopolitical instability (such as the current conflict between Russia and Ukraine and related economic and other retaliatory measures taken by the United States, European Union and others), pandemics (such as the ongoing COVID-19 pandemic), inflationary pressures (such as current inflation related to global supply chain disruptions), extreme weather conditions and natural disasters, market declines and uncertainty, fluctuating interest and foreign currency rates and credit availability, government austerity measures, fluctuating fuel and other energy costs, fluctuating commodity prices, and general uncertainty regarding the overall future economic environment. In particular, the ultimate impact of the conflict in Ukraine on fuel prices, inflation, volatility of global financial markets, the global supply chain and other macroeconomic conditions is unknown and could materially adversely affect the availability and cost of materials, access to capital, global economic growth, consumer confidence and demand for our products and services.

Our customers may respond to such economic pressures by reducing or deferring their capital spending or reducing staff. Furthermore, unfavorable changes in foreign exchange rates versus USD could increase our product and labor costs, thus reducing our gross profit.

***We face competition from many sources, including larger companies and new entrants, and we may be unable to compete successfully.***

There are a number of dialysis machine manufacturers in the United States, Europe and Asia. Notable competitors in the United States include Fresenius Medical Care AG & Co. KGaA (Fresenius), Baxter International, Inc. (Baxter) and B. Braun Medical Inc. (B. Braun). In addition, Quanta Dialysis Technologies Ltd's (Quanta) dialysis system received FDA 510(k) clearance for use in acute and/or chronic settings. Of these competitors, Fresenius is the largest and it supplies dialysis products, operates a significant number of dialysis clinics and provides outsourced dialysis services in many hospitals. Fresenius, Baxter and B. Braun all supply machines and supplies in both the acute and home care settings. With the exception of Quanta, all of these organizations are currently significantly larger with greater financial and personnel resources than us, enjoy significantly greater market share than ours and have greater resources than we do. As a consequence, they are able to spend more on product development, marketing, sales and other product initiatives than we can. Additionally, companies with dialysis machine development programs include Medtronic plc and CVS Health Corp. Some of our competitors have:

- substantially greater name recognition;
- broader, deeper or longer-term relations with healthcare professionals, customers and third-party payors;
- more established distribution networks;
- additional lines of products and the ability to offer rebates or bundle products to offer greater discounts or other incentives to gain a competitive advantage;
- greater experience in conducting research and development, manufacturing, clinical trials, marketing and obtaining regulatory clearance or approval for products; and
- greater financial and human resources for product development, sales and marketing and patent litigation.

Our continued success depends on our ability to:

- further penetrate the acute care market and drive utilization and fleet expansion among our existing customers in the acute care setting;
- successfully expand within the home dialysis market;
- maintain and widen our technology lead over competitors by continuing to innovate and deliver new product enhancements on a continuous basis;
- cost-effectively manufacture Tablo and its component parts as well as drive down the cost of service; and
- increase adoption of Tablo in the chronic outpatient facility setting via transitional care programs within existing dialysis clinics.

In addition, competitors, including those with greater financial resources than ours, could acquire, combine with or partner with other companies to gain enhanced name recognition and market share, as well as new technologies, products or services that could effectively compete with our existing solutions, which may cause our revenue to decline and would harm our business. For example, in March 2022, Fresenius Health Partners (the value-based care division of Fresenius), InterWell Health and Cricket Health, Inc. entered into a definitive agreement to merge the three businesses into a new independent company.

Our competitors also compete with us in recruiting and retaining qualified scientific, management and commercial personnel, as well as in acquiring technologies complementary to, or necessary for, Tablo. Because of the complex and technical nature of Tablo and the dynamic market in which we compete, any failure to attract and retain a sufficient number of qualified employees could materially harm our ability to develop and commercialize Tablo, which would have a material adverse effect on our business, financial condition and results of operations.

As we attain greater commercial success, our competitors are likely to develop products that offer features and functionality similar to Tablo. Improvements in existing competitive products or the introduction of new competitive products may make it more difficult for us to compete for sales, particularly if those competitive products demonstrate better reliability, convenience or effectiveness or are offered at lower prices.

More generally, the development of viable medical, pharmacological and technological advances in treating or preventing kidney failure may also limit the opportunity for Tablo and our services. While kidney transplantation is the treatment of choice for most patients with ESRD, it is not currently a viable treatment for most patients. This may change, however, with the development of new medications designed to reduce the incidence of kidney transplant rejection, progress in using kidneys harvested from genetically engineered animals as a source of transplants as demonstrated by the first pig-to-human kidney transplant in September 2021, and other advances in kidney transplantation.

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

### (a) Sales of Unregistered Securities

Not applicable.

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

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

### (c) Repurchases

Not applicable.

## Item 3. Defaults Upon Senior Securities.

None.

## Item 4. Mine Safety Disclosures.

Not applicable.

**Item 5. Other Information.**

None.

## Item 6. Exhibits.

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

* Filed herewith.

## SIGNATURES

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

| | | |
|---|---|---|
| | | Outset Medical, Inc. |
| Date: May 4, 2022 | By: | /s/ Leslie Trigg<br>Leslie Trigg<br>President and Chief Executive Officer<br>(*Principal Executive Officer*) |
| Date: May 4, 2022 | By: | /s/ Nabeel Ahmed<br>Nabeel Ahmed<br>Chief Financial Officer<br>(*Principal Financial and Accounting Officer*) |

**Exhibit 31.1**

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

I, Leslie Trigg, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 4, 2022

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

**Exhibit 31.2**

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

I, Nabeel Ahmed, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: May 4, 2022

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

**Exhibit 32.1**

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

In connection with the Quarterly Report of Outset Medical, Inc. (the “Company”) on Form 10-Q for the period ending March 31, 2022, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), each of the undersigned certifies, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, to her/his knowledge:

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

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

| | | |
|---|---|---|
| May 4, 2022 | By: | /s/ Leslie Trigg<br>Leslie Trigg<br>Chief Executive Officer<br>(*Principal Executive Officer*) |
| May 4, 2022 | By: | /s/ Nabeel Ahmed<br>Nabeel Ahmed<br>Chief Financial Officer<br>(*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.