

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549**

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): February 13, 2023

Outset Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39513

(Commission File Number)

20-0514392
(IRS Employer
Identification No.)

**3052 Orchard Dr.,
San Jose, California**
(Address of Principal Executive Offices)

95134
(Zip Code)

Registrant's Telephone Number, Including Area Code: (669) 231-8200

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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, \$0.001 par value per share	OM	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

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.

Item 2.02 Result of Operations and Financial Condition.

On February 13, 2023, Outset Medical, Inc. (the “Company”) issued a press release and will hold its fourth quarter and full year 2022 earnings conference call announcing the Company’s financial results for the quarter and year ended December 31, 2022. A copy of the press release is furnished herewith as Exhibit 99.1 and incorporated herein by reference.

The information contained in this Item 2.02 and Exhibits 99.1 hereto shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

Item 5.02 Departure of Directors of Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On February 13, 2023, Martin Vazquez informed the Company of his decision to retire from his role as Chief Operating Officer of the Company effective April 3, 2023 to pursue personal opportunities. Mr. Vazquez’s departure was not due to any dispute or disagreement with the Company or its management. We expect Mr. Vazquez to enter into a consulting arrangement with the Company to provide certain consulting services for a minimum of six months following the effective date of his resignation. The Compensation Committee of the Company’s Board of Directors also took action to provide that if Mr. Vazquez successfully completes the term of the consulting arrangement described above, then the unvested portion of certain stock options granted to Mr. Vazquez on February 3, 2020 to purchase 72,151 shares of common stock of the Company, and having an exercise price of \$8.62 per share, will become fully vested and exercisable. If earned, the number of option grant shares subject to accelerated vesting will be approximately 6,013 shares.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release entitled “Outset Medical Reports Fourth Quarter and Full Year 2022 Financial Results” dated February 13, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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: February 13, 2023

By: _____
/s/Nabeel Ahmed
Nabeel Ahmed
Chief Financial Officer

Outset Medical Reports Fourth Quarter and Full Year 2022 Financial Results

San Jose, CA – February 13, 2023 – Outset Medical, Inc. (Nasdaq: OM) (“Outset” or the “Company”), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis, today reported financial results for the fourth quarter and full year ended December 31, 2022.

Recent Highlights

- Recorded net revenue of \$32.0 million in the fourth quarter, a 15.3% increase compared to \$27.8 million in the third quarter, and a 14.0% increase compared to \$28.2 million in the fourth quarter of 2021. Revenue for the full year was \$115.4 million, an increase of 12.4% compared to \$102.6 million in 2021
- Achieved gross margin for the fourth quarter of 16.5% (17.1% on a non-GAAP basis), compared to 11.8% (12.0% on a non-GAAP basis) in the fourth quarter of 2021. Gross margin for the full year was 15.5% (16.1% on a non-GAAP basis), an increase of more than 800 basis points over 2021
- Increased the Tablo year-end installed base 54% year-over-year to approximately 4,000 systems, including 3,200 with acute- and sub-acute care providers and a more than doubling of units with home providers to nearly 800
- Initiated the production of Tablo cartridges at Outset’s Mexico manufacturing site as part of the company’s long-term gross margin expansion and supply continuity strategies.

“Growth in the fourth quarter exceeded our expectations as we saw Tablo’s economic and clinical advantages continue to gain traction with dialysis providers and their patients across our end markets,” said Leslie Trigg, Chair and Chief Executive Officer of Outset. “At the same time, we continued to expand gross margins and gain operating leverage, particularly in our sales and field service organizations. As we exit 2022 and look ahead to 2023, I want to thank the ever-expanding community of hospital leaders, dialysis nurses and nephrologists who share our focus on improving the lives of dialysis patients by challenging and changing the status quo.”

Fourth Quarter 2022 Financial Results

Revenue for the fourth quarter of 2022 was \$32.0 million, representing an increase of 14.0% compared to \$28.2 million in the fourth quarter of 2021. Product revenue was \$26.4 million, representing an increase of 11.5% compared to \$23.7 million in the fourth quarter of 2021. Service and other revenue was \$5.6 million, representing an increase of 25.3% compared to \$4.5 million in the fourth quarter of 2021.

Total gross profit was \$5.3 million, compared to \$3.3 million for the fourth quarter of 2021. Total gross margin was 16.5%, compared to 11.8% in the fourth quarter of 2021. On a non-GAAP basis, gross margin improved to 17.1% from 12.0% in the fourth quarter of 2021. Product gross profit was \$4.3 million, compared to \$2.2 million of product gross loss in the fourth quarter of 2021. Product gross margin was 16.4%, compared to 9.3% in the fourth quarter of 2021. Service and other gross profit was \$1.0 million, compared to \$1.1 million of service and other gross profit in the fourth quarter of 2021. Service and other gross margin was 17.0%, compared to 25.1% in the fourth quarter of 2021.

Operating expenses were \$45.1 million, including research and development (R&D) expenses of \$11.4 million, sales and marketing (S&M) expenses of \$23.6 million, and general and administrative (G&A) expenses of \$10.0 million. This compared to operating expenses of \$44.1 million, including R&D expenses of \$11.4 million, S&M expenses of \$23.0 million, and G&A expenses of \$9.7 million in the fourth quarter of 2021.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$38.0 million, including R&D expenses of \$9.5 million, S&M expenses of \$20.8 million, and G&A expenses of \$7.7 million.

Net loss was (\$41.4) million, or (\$0.86) per share, compared to net loss of (\$41.2) million, or (\$0.87) per share, for the same period in 2021. On a non-GAAP basis, net loss was (\$34.1) million, or (\$0.71) per share, compared to non-GAAP net loss of (\$36.4) million, or (\$0.77) per share for the same period in 2021.

Total cash, including restricted cash, cash equivalents and short-term investments, was \$290.8 million as of December 31, 2022, compared to \$260.8 million as of September 30, 2022.

Full Year 2022 Financial Results

Revenue for 2022 was \$115.4 million, representing an increase of 12.4% compared to \$102.6 million for 2021. Product revenue was \$93.4 million, representing an increase of 10.8% compared to \$84.3 million for 2021. Service and other revenue was \$22.0 million, representing an increase of 20.2% compared to \$18.3 million for 2021.

Total gross profit was \$17.8 million, compared to \$7.6 million for 2021. Total gross margin was 15.5%, compared to 7.4% in 2021. Product gross loss was \$10.9 million, compared to (\$0.3) million of product gross loss in 2021. Product gross margin was 11.6%, compared to (0.4)% in 2021. Service and other gross profit was \$7.0 million, compared to \$7.9 million of service and other gross profit in 2021. Service and other gross margin was 31.6%, compared to 43.4% in 2021.

Operating expenses were \$178.9 million, including R&D expenses of \$48.9 million, S&M expenses of \$89.5 million, and G&A expenses of \$40.5 million. This compared to operating expenses of \$138.1 million, including R&D expenses of \$36.7 million, S&M expenses of \$65.1 million, and G&A expenses of \$36.3 million for 2021.

Excluding stock-based compensation expense, non-GAAP operating expenses were \$152.4 million, including R&D expenses of \$42.0 million, S&M expenses of \$79.2 million, and G&A expenses of \$31.1 million.

Net loss attributable to common stockholders was (\$163.0) million, or (\$3.38) per share, compared to a net loss attributable to common stockholders of (\$131.9) million, or (\$2.89) per share, for 2021. On a non-GAAP basis, net loss was (\$135.8) million, or (\$2.82) per share, compared to a non-GAAP net loss of (\$117.4) million, or (\$2.57) per share for 2021.

Full Year 2023 Financial Guidance

Outset reaffirmed its previously provided guidance for 2023, including revenue of \$140 million to \$150 million, growing approximately 22% to 30% over 2022, and non-GAAP gross margin of approximately 20% for 2023, exiting the year in the mid-20% range for the fourth quarter.

Webcast and Conference Call Details

Outset will host a conference call today, February 13, 2023, at 2:00 p.m. PT / 5:00 p.m. ET to discuss its fourth quarter and full year 2022 financial results. Those interested in listening to the conference call may do so by registering online. Once registered, participants will receive dial-in numbers and a unique pin to join the call. Participants are encouraged to register more than 15 minutes before the start of the call. A live webcast of the conference call will be available on the Investor Relations section of the Company's website at <https://investors.outsetmedical.com>. The webcast will be archived on the website following the completion of the call.

Use of Non-GAAP Financial Measures

The Company may report non-GAAP results for gross profit/loss, gross margin, operating expenses, operating margins, net income/loss, basic and diluted net income/loss per share, other income/loss, and cash flows. These non-GAAP financial measures are in addition to, and not a substitute for, or superior to, financial measures calculated in accordance with GAAP. The Company's financial measures under GAAP include stock-based compensation expense, as listed in the itemized reconciliations between GAAP and non-GAAP financial measures included in this press release. Management has excluded the effects of this non-cash expense item in non-GAAP measures to assist investors in analyzing and assessing past and future operating performance and period-to-period comparisons. There are limitations related to the use of non-GAAP financial measures because they are not prepared in accordance with GAAP, may exclude significant expenses required by GAAP to be recognized in the Company's financial statements, and may not be comparable to non-GAAP financial measures used by other companies. The Company encourages investors to carefully consider its results under GAAP, as well as its supplemental non-GAAP information and the reconciliation between these presentations, to more fully understand its business. Reconciliations between GAAP and non-GAAP results are presented in the Appendix A of this press release.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. All statements other than statements of

historical fact are forward-looking statements. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, which affect or may affect the Company's business, strategy, operations or financial performance, and actual results and other events may differ materially from those expressed or implied in such statements due to numerous risks and uncertainties. Forward-looking statements include, but are not limited to, statements about the Company's possible or assumed future results of operations and financial position, including expectations regarding projected revenues (including sales into the home market and such sales as a percentage of revenues), gross margin, operating expenses, capital expenditures, profitability and outlook; statements regarding the Company's overall business strategy, plans and objectives of management; the Company's expectations regarding the market sizes and growth potential for Tablo and the total addressable market opportunities for Tablo; continued execution of the Company's initiatives designed to reduce the cost of producing and shipping our products, expand gross margins, further secure supply continuity and otherwise mitigate supply chain challenges and its ability to achieve projected cost reductions and other anticipated benefits from these initiatives at the levels or within the timeframe estimated; as well as the Company's expectations regarding the impact of macroeconomic factors on the Company, its customers and suppliers. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified. Factors that could cause actual results or other events to differ materially from those contemplated in this press release can be found in the Risk Factors section of the Company's public filings with the Securities and Exchange Commission, including its latest annual and quarterly reports. Because forward-looking statements are inherently subject to risks and uncertainties, you should not rely on these forward-looking statements as predictions of future events. These forward-looking statements speak only as of their date and, except to the extent required by law, the Company undertakes no obligation to update these statements, whether as a result of any new information, future developments or otherwise.

About Outset Medical, Inc.

Outset is a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis. The Tablo® Hemodialysis System, FDA cleared for use from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients and operationally simplifies it for providers. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime, anywhere and by anyone. The integration of water purification and on-demand dialysate production enables Tablo to serve as a dialysis clinic on wheels, with 2-way wireless data transmission and a proprietary data analytics platform powering a new holistic approach to dialysis care. Tablo is a registered trademark of Outset Medical, Inc.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Revenue:				
Product revenue	\$ 26,364	\$ 23,650	\$ 93,388	\$ 84,312
Service and other revenue	5,643	4,502	21,987	18,290
Total revenue	<u>32,007</u>	<u>28,152</u>	<u>115,375</u>	<u>102,602</u>
Cost of revenue:				
Cost of product revenue ⁽²⁾	22,050	21,459	82,510	84,639
Cost of service and other revenue	4,684	3,372	15,032	10,355
Total cost of revenue	<u>26,734</u>	<u>24,831</u>	<u>97,542</u>	<u>94,994</u>
Gross profit ⁽¹⁾	5,273	3,321	17,833	7,608
Gross margin ⁽¹⁾	16.5 %	11.8 %	15.5 %	7.4 %
Operating expenses:				
Research and development ⁽²⁾	11,444	11,410	48,855	36,741
Sales and marketing ⁽²⁾	23,631	22,991	89,482	65,070
General and administrative ⁽²⁾	10,022	9,719	40,515	36,316
Total operating expenses	<u>45,097</u>	<u>44,120</u>	<u>178,852</u>	<u>138,127</u>
Loss from operations	(39,824)	(40,799)	(161,019)	(130,519)
Interest income and other income, net	1,907	123	3,291	498
Interest expense	(2,096)	(431)	(3,566)	(1,715)
Loss on extinguishment of term loan	(1,367)	—	(1,367)	—
Loss before provision for income taxes	(41,380)	(41,107)	(162,661)	(131,736)
Provision for income taxes	64	125	295	199
Net loss	<u>\$ (41,444)</u>	<u>\$ (41,232)</u>	<u>\$ (162,956)</u>	<u>\$ (131,935)</u>
Net loss per share, basic and diluted	<u>\$ (0.86)</u>	<u>\$ (0.87)</u>	<u>\$ (3.38)</u>	<u>\$ (2.89)</u>
Shares used in computing net loss per share, basic and diluted	<u>48,375</u>	<u>47,169</u>	<u>48,161</u>	<u>45,589</u>

⁽¹⁾ Gross profit and gross margin by source consisted of the following:

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Gross profit				
Product revenue	\$ 4,314	\$ 2,191	\$ 10,878	\$ (327)
Service and other revenue	959	1,130	6,955	7,935
Total gross profit	<u>\$ 5,273</u>	<u>\$ 3,321</u>	<u>\$ 17,833</u>	<u>\$ 7,608</u>
Gross margin				
Product revenue	16.4 %	9.3 %	11.6 %	(0.4) %
Service and other revenue	17.0 %	25.1 %	31.6 %	43.4 %
Total gross margin	16.5 %	11.8 %	15.5 %	7.4 %

⁽²⁾ Include stock-based compensation expense as follows:

	Three Months Ended December 31,		Years Ended December 31,	
	2022	2021	2022	2021
Cost of revenue	\$ 208	\$ 68	\$ 701	\$ 205
Research and development	1,960	1,241	6,845	3,049
Sales and marketing	2,829	1,896	10,269	4,690
General and administrative	2,356	1,587	9,388	6,637
Total stock-based compensation expense	<u>\$ 7,353</u>	<u>\$ 4,792</u>	<u>\$ 27,203</u>	<u>\$ 14,581</u>

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

	December 31,	
	2022 (Unaudited)	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 73,222	\$ 182,348
Short-term investments	214,280	157,140
Accounts receivable, net	28,070	25,600
Inventories	51,476	39,185
Prepaid expenses and other current assets	6,597	5,529
Total current assets	373,645	409,802
Restricted cash	3,311	33,311
Property and equipment, net	15,876	12,964
Operating lease right-of-use assets	6,117	7,231
Other assets	1,166	156
Total assets	<u>\$ 400,115</u>	<u>\$ 463,464</u>
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	\$ 603	\$ 1,763
Accrued compensation and related benefits	21,519	24,948
Accrued expenses and other current liabilities	16,227	13,789
Accrued warranty liability	3,620	3,704
Deferred revenue, current	8,662	6,340
Operating lease liabilities, current	1,318	1,151
Total current liabilities	51,949	51,695
Accrued interest	113	721
Deferred revenue	151	312
Operating lease liabilities	5,576	6,893
Term loan	96,336	29,762
Total liabilities	<u>154,125</u>	<u>89,383</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 5,000 shares authorized, and no shares issued and outstanding as of December 31, 2022 and December 31, 2021	—	—
Common stock, \$0.001 par value; 300,000 shares authorized as of December 31, 2022 and December 31, 2021; 48,465 and 47,241 shares issued and outstanding as of December 31, 2022 and December 31, 2021, respectively	48	47
Additional paid-in capital	1,035,456	1,000,212
Accumulated other comprehensive loss	(564)	(184)
Accumulated deficit	(788,950)	(625,994)
Total stockholders' equity	<u>245,990</u>	<u>374,081</u>
Total liabilities and stockholders' equity	<u>\$ 400,115</u>	<u>\$ 463,464</u>

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

	Years Ended December 31,	
	2022	2021
Net cash used in operating activities	\$ (145,729)	\$ (130,264)
Net cash used in investing activities	(66,295)	(142,507)
Net cash provided by financing activities	72,898	160,147
Net decrease in cash, cash equivalents and restricted cash	(139,126)	(112,624)
Cash, cash equivalents and restricted cash at beginning of the period	215,659	328,283
Cash, cash equivalents and restricted cash at end of the period ⁽¹⁾	\$ 76,533	\$ 215,659

⁽¹⁾ The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the accompanying condensed balance sheets that sum to the total of the amounts shown in the accompanying condensed statements of cash flows (in thousands):

	December 31,	
	2022	2021
Cash and cash equivalents	\$ 73,222	\$ 182,348
Restricted cash	3,311	33,311
Total cash, cash equivalents and restricted cash*	\$ 76,533	\$ 215,659

* The total cash, including restricted cash, cash equivalents and investment securities as of December 31, 2022 was \$290.8 million; compared to \$372.8 million as of December 31, 2021.

Outset Medical, Inc.
Results of Operations – Non-GAAP
(in thousands, except per share amounts)
(unaudited)

Reconciliation between GAAP and non-GAAP net loss per share:

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
GAAP net loss per share, diluted	\$ (0.86)	\$ (0.87)	\$ (3.38)	\$ (2.89)
Stock-based compensation expense	0.15	0.10	0.56	0.32
Non-GAAP net loss per share, diluted	<u>\$ (0.71)</u>	<u>\$ (0.77)</u>	<u>\$ (2.82)</u>	<u>\$ (2.57)</u>

Reconciliation between GAAP and non-GAAP net loss:

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
GAAP net loss, diluted	\$ (41,444)	\$ (41,232)	\$ (162,956)	\$ (131,935)
Stock-based compensation expense	7,353	4,792	27,203	14,581
Non-GAAP net loss, diluted	<u>\$ (34,091)</u>	<u>\$ (36,440)</u>	<u>\$ (135,753)</u>	<u>\$ (117,354)</u>

Reconciliation between GAAP and non-GAAP results of operations:

	Three Months Ended		Years Ended	
	December 31,		December 31,	
	2022	2021	2022	2021
GAAP gross profit	\$ 5,273	\$ 3,321	\$ 17,833	\$ 7,608
Stock-based compensation expense	208	68	701	205
Non-GAAP gross profit	<u>\$ 5,481</u>	<u>\$ 3,389</u>	<u>\$ 18,534</u>	<u>\$ 7,813</u>
GAAP gross margin	16.5 %	11.8 %	15.5 %	7.4 %
Stock-based compensation expense	0.6	0.2	0.6	0.2
Non-GAAP gross margin	<u>17.1 %</u>	<u>12.0 %</u>	<u>16.1 %</u>	<u>7.6 %</u>
GAAP research and development expense	\$ 11,444	\$ 11,410	\$ 48,855	\$ 36,741
Stock-based compensation expense	(1,960)	(1,241)	(6,845)	(3,049)
Non-GAAP research and development expense	<u>\$ 9,484</u>	<u>\$ 10,169</u>	<u>\$ 42,010</u>	<u>\$ 33,692</u>
GAAP sales and marketing expense	\$ 23,631	\$ 22,991	\$ 89,482	\$ 65,070
Stock-based compensation expense	(2,829)	(1,896)	(10,269)	(4,690)
Non-GAAP sales and marketing expense	<u>\$ 20,802</u>	<u>\$ 21,095</u>	<u>\$ 79,213</u>	<u>\$ 60,380</u>
GAAP general and administrative expense	\$ 10,022	\$ 9,719	\$ 40,515	\$ 36,316
Stock-based compensation expense	(2,356)	(1,587)	(9,388)	(6,637)
Non-GAAP general and administrative expense	<u>\$ 7,666</u>	<u>\$ 8,132</u>	<u>\$ 31,127</u>	<u>\$ 29,679</u>
GAAP total operating expense	\$ 45,097	\$ 44,120	\$ 178,852	\$ 138,127
Stock-based compensation expense	(7,145)	(4,724)	(26,502)	(14,376)
Non-GAAP total operating expense	<u>\$ 37,952</u>	<u>\$ 39,396</u>	<u>\$ 152,350</u>	<u>\$ 123,751</u>

