
**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): January 27, 2026

Outset Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-39513

20-0514392
(IRS Employer
Identification No.)

(Commission File Number)

**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 8.01 Other Events

On January 27, 2026, Outset Medical, Inc. (the “Company”) announced that the U.S. Food and Drug Administration granted 510(k) clearance for its next-generation Tablo platform, which the Company expects to begin shipping to customers in the second quarter of 2026. A copy of the press release is attached hereto as Exhibit 99.1.

Forward-Looking Statements

This report and the exhibit attached hereto contain 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 regarding the anticipated

launch and timing of product enhancements and new features, as well as new or expanded services, and the expected benefits, performance, and impact thereof. 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 report and the exhibit attached hereto 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release entitled “Next-Generation Tablo Hemodialysis System Receives FDA Clearance, Second Quarter Launch Planned” dated January 27, 2026
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: January 27, 2026

By: _____ /s/ John Brottem

John Brottem
General Counsel

Next-Generation Tablo Hemodialysis System Receives FDA Clearance, Second Quarter Launch Planned

Tablo becomes first dialysis system to clear FDA's most rigorous cybersecurity standards

San Jose, CA – Jan. 27, 2026 – Outset Medical, Inc. (Nasdaq: OM), a medical technology company pioneering a first-of-its-kind technology to improve clinical outcomes in dialysis with less cost and complexity, today announced 510(k) clearance by the U.S. Food and Drug Administration (FDA) of its next-generation Tablo platform, designed to deliver enterprise-level security, reliability and connectivity for hospitals, health systems and home providers of dialysis.

With the clearance, Tablo becomes the first hemodialysis system incorporating FDA's most rigorous and recent guidance on medical device cybersecurity published in June 2025. Additionally, enhancements to the hardware, operating system and software have been designed to further enhance Tablo's reliability and user experience.

"We are proud to be the first dialysis company to clear the high standard for cybersecurity set by the FDA, a milestone that reflects Outset's ongoing commitment to innovation, patient safety and data stewardship," said Leslie Trigg, Chair and CEO. "Our next-generation platform is designed to protect and amplify the clinical, financial and operational value delivered to our customers, and extend Outset's technology lead."

Next-Generation Tablo Platform

The new Tablo platform is architected to offer enterprise-grade cybersecurity, reliability, and usability.

- **Enterprise Cybersecurity:** Security is embedded at the hardware, software and cloud level designed to meet today's hospital information technology standards.
- **Device Performance:** Operating system modernization, hardware upgrades and software advancements improve system performance and are designed to lengthen the time between planned maintenance in high-acuity environments.
- **Exterior Enhancements:** A new exterior aimed at providing hospital-grade durability that withstands the rigors of acute environments.

The next-generation Tablo platform is expected to begin shipping to customers in the second quarter of 2026. Healthcare providers currently using Tablo will be eligible to upgrade to the new cybersecurity platform.

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. These forward-looking statements include, without limitation, statements regarding the anticipated launch and timing of product enhancements and new features, as well as new or expanded services, and the expected benefits, performance, and impact thereof. Forward-looking statements are based on management's current assumptions and expectations of future events and trends, and are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, which could cause actual results and other events to differ materially from those expressed or implied in such statements. These risks and uncertainties include risks described in the Risk Factors section of Outset's public filings with the U.S. Securities and Exchange Commission, including its latest annual and quarterly reports. These forward-looking statements speak only as of the date hereof and should not be unduly relied upon. Outset disclaims any obligation to update these forward-looking statements.

About Outset Medical, Inc.

Outset is a medical technology company transforming the dialysis experience across the continuum of care with a first-of-its-kind technology. The Tablo® Hemodialysis System, FDA-cleared for use from hospital to home, is trusted by more than 1,000 U.S. healthcare facilities and has enabled millions of treatments delivered by thousands of nurses. Designed to reduce the cost and complexity of dialysis, Tablo combines water purification and on-demand dialysate production into a single, integrated system that connects seamlessly with Electronic Medical Record systems and a proprietary data analytics

platform. This enterprise solution empowers providers to develop an in-house dialysis program where they are in control – enabling better operational, clinical, and financial outcomes. Outset is redefining what’s possible in kidney care through innovation, scale, and a relentless commitment to improving the lives of patients and the professionals who care for them. For more information, visit www.outsetmedical.com.

Investor Contact

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