



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

January 27, 2026

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

SAN JOSE, Calif., Jan. 27, 2026 (GLOBE NEWSWIRE) -- 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.

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