



## Outset Medical Announces Resolution of Warning Letter

February 13, 2025

SAN JOSE, Calif., Feb. 13, 2025 (GLOBE NEWSWIRE) -- Outset Medical, Inc. (Nasdaq: OM) ("Outset"), a medical technology company pioneering a first-of-its-kind technology to reduce the cost and complexity of dialysis, today announced it has been notified by the Food and Drug Administration that all issues cited in a Warning Letter the company received in July of 2023 have been addressed.

"A commitment to innovation and the advancement of better outcomes in dialysis remains at the core of Outset, which makes the quality of our products and regulatory compliance essential to our company's success," said Leslie Trigg, Chair and Chief Executive Officer. "We are pleased to achieve this important milestone and remain vigilant as we work to continuously improve everything we do on behalf of the patients and providers we serve."

### **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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