



Outset Medical Announces Shipment Hold on New Tablo Systems for Home Use Pending FDA Review and Clearance of Recent 510(K) Submission

June 13, 2022

Investor Webcast and Conference Call Scheduled for 5:00 p.m. EST

SAN JOSE, Calif.--(BUSINESS WIRE)--Jun. 13, 2022-- Outset Medical, Inc. (Nasdaq: OM) ("Outset" or the "company") today announced it has implemented a shipment hold on the distribution of its Tablo Hemodialysis System for home use pending the Food and Drug Administration's (FDA) review and clearance of a 510(k) the company submitted for changes made since the device's original March 2020 clearance.

Outset has not identified any safety issues with Tablo. The company will continue to market and ship Tablo for use by healthcare professionals in chronic and acute care settings. Devices that are already distributed to home users have not been removed and current users can continue to work with their healthcare providers on appropriate treatment.

As a result of the shipment hold, Outset now expects second quarter 2022 revenue of at least \$25 million. The company anticipates an update on the status of the regulatory review process in the third quarter and to provide an update to its 2022 revenue and other financial goals during its next quarterly update in early August. Until then, the company has suspended its prior guidance.

Webcast and Conference Call Details

Outset will host a conference call today at 2:00 p.m. PT/ 5:00 p.m. ET to discuss today's updates. The dial-in numbers are (833) 614-1409 for domestic callers and (914) 987-7130 for international callers. The conference ID is 9710708. 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.

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, statements regarding the Company's shipment hold of new Tablo shipments for home use including anticipated impacts thereof and potential timing for resuming such shipments and statements regarding the Company's anticipated regulatory review and approval timeline and process. 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 include the Company's ability to obtain necessary clearances or approvals for its products on a timely basis or at all, as well as other factors which can be found in the Risk Factors section of Outset's public filings with the Securities and Exchange Commission, including Outset's 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. Tablo serves as a single enterprise solution that can be utilized across the continuum of care, allowing dialysis to be delivered anytime and anywhere. 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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Investor Contact

Jim Mazzola
858-342-8272
jmazzola@outsetmedical.com

Media Contact

Nicole Shannon
nshannon@outsetmedical.com

Source: Outset Medical, Inc.