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): May 6, 2024

Outset Medical, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-39513**	**20-0514392**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
3052 Orchard Dr., San Jose, California		**95134**
(Address of Principal Executive Offices)		**(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 May 6, 2024, Outset Medical, Inc. (the "Company") announced that the United States Food and Drug Administration has granted 510(k) clearance of TabloCart with Prefiltration. The Company has resumed distribution of TabloCart with Prefiltration and has product available to ship to customers in the United States. A copy of the press release is attached hereto as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit Number	Description
99.1	Press Release entitled "Outset Medical's TabloCart with Prefiltration Receives FDA 510(k) Clearance" dated May 6, 2024
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: May 6, 2024

By: /s/Nabeel Ahmed

Nabeel Ahmed
Chief Financial Officer

Exhibit 99.1

Outset Medical's TabloCart with Prefiltration Receives FDA 510(k) Clearance

SAN JOSE, Calif. – May 6, 2024 -- 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, announced today that the U.S. Food and Drug Administration (FDA) has granted 510(k) clearance of TabloCart™ with prefiltration, an innovative optional accessory for the Tablo® Hemodialysis System.

Outset has resumed distribution of TabloCart with prefiltration and has product available to ship to customers in the United States.

"With the FDA's clearance of TabloCart with prefiltration, we have delivered features to the Tablo Hemodialysis System that increase the flexibility for nurses and health systems to serve patients from the ICU to the bedside,” said Leslie Trigg, Chair and CEO of Outset Medical. “Today’s announcement underscores Outset Medical's commitment to innovation and our ongoing dedication to transforming the landscape of dialysis treatment.”

TabloCart is designed to enhance the user experience within healthcare facilities. It comes in two versions: one with added storage and another featuring water prefiltration capabilities, meeting diverse clinical needs. Key features of TabloCart include:

- **Versatile prefiltration**: With its three customizable prefiltration options, TabloCart is designed to adapt to varying water conditions and also features a booster pump to increase incoming water pressure.
- **Enhanced maneuverability**: Equipped with 360-degree rotating wheels and directional locking rear wheels, it facilitates seamless movement through various clinical environments.

TabloCart is an innovative optional accessory that complements the Tablo Hemodialysis System. Tablo, which is used from the hospital to the home, represents a significant technological advancement that transforms the dialysis experience for patients, and operationally simplifies it for providers. Requiring only access to tap water and a standard electrical outlet, 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 virtually anyone.

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.

Indications for Use

The Tablo® Hemodialysis System and TabloCart™ is indicated for use in patients with acute and/or chronic renal failure, with or without ultrafiltration, in an acute or chronic care facility. Treatments must be administered under physician's prescription and observed by a trained individual who is considered competent in the use of the device. The Tablo Hemodialysis System is also indicated for use in the home. Treatment types available include Intermittent Hemodialysis (IHD), Sustained Low Efficiency Dialysis (SLED/ SLEDD), Prolonged Intermittent Renal Replacement Therapy (PIRRT), and Isolated Ultrafiltration.

For more information:

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