

The Law Offices of Timothy L. Miles Reminds Investors of a Class Action Lawsuit Against Outset Medical, Inc. (OM)

Class action lawsuit charges Outset Medical and certain of its top executive officers with violations of the Securities Exchange Act of 1934.

NASHVILLE, TENNESSEE, UNITED STATES, July 18, 2022 /EINPresswire.com/ -- The Law Offices of [Timothy L. Miles](#), who has been leading the fight to protect shareholder rights for over 20 years, reminds investors that a purchaser of Outset Medical Inc. filed a class action complaint against the Company for alleged violations of the Securities

Exchange Act of 1934. The Outset Medical class action lawsuit seeks to represent purchasers or acquirers of Outset Medical, Inc. (NASDAQ: OM) common stock between September 15, 2020 and June 13, 2022, inclusive (the "Class Period"). The Outset Medical class action lawsuit –

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Outset Medical Shareholders Urged to Contact the Firm for Additional Information and a Free Case Evaluation”

Timothy L. Miles

captioned Plymouth County Retirement Association v. Outset Medical, Inc., No. 22-cv-04016 (N.D. Cal.) – charges Outset Medical and certain of its top executive officers with violations of the Securities Exchange Act of 1934.

If you suffered losses in Outset Medical or would like more information, [visit us here](#).

Outset Medical Mislead Investors

Outset Medical’s flagship product is the Tablo Hemodialysis System, a dialysis machine that purifies tap water and then artificially purifies and removes toxins from the blood of patients suffering from kidney failure.



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FIRM ANNOUNCEMENT

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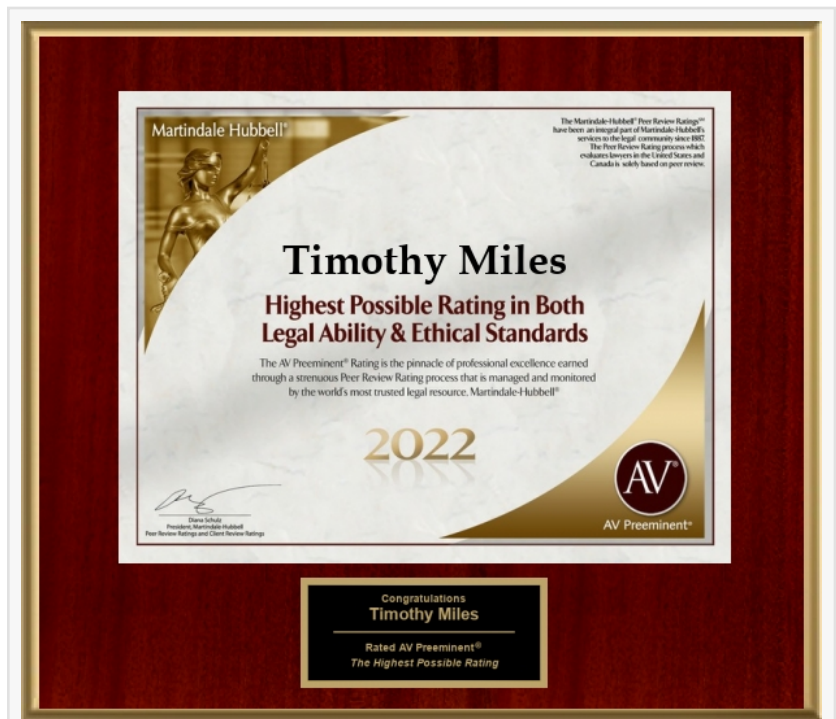
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Nationally Recognized Shareholder Rights Attorney
Timothy L. Miles

Throughout the Class Period, Outset Medical touted that Tablo can “serve as a dialysis clinic on wheels” that had been “cleared by the [U.S.] Food and Drug Administration (FDA) for use in the hospital, clinic or home setting.” However, devices used by non-professionals outside of a clinical setting and that can present serious health consequences like Tablo are subject to heightened scrutiny by the FDA, including post-market surveillance studies. Thus, though cleared by the FDA for sale, Tablo for use in the home setting was subject to additional studies, the results of which could require additional applications for clearance and approvals. And while performing further regulatory studies during the Class Period, Outset Medical assured investors that it was conducting the studies “in accordance with the FDA approved protocol,” which required an appropriate demonstration of “real-world” human testing given that the device would be used at home by non-professionals.

But as the Outset Medical class action lawsuit alleges, undisclosed to investors, Outset Medical continuously made significant changes to Tablo for use in the home setting. The nature of these undisclosed changes: (i) made it likely that the FDA would order Outset Medical to cease all marketing and selling of Tablo for use in the home pending additional applications and approvals; and (ii) prevented Outset Medical from performing the requisite “real-world” human testing on a device cleared for sale, contrary to representations to investors.

On May 4, 2022, Tablo Medical announced disappointing results for the first quarter of 2022, which analysts attributed, among other things, to the untested nature of Tablo in the home setting. On this news, the price of Outset Medical common stock declined more than 40% over the three trading days that followed.



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Then, on June 13, 2022, Outset Medical announced that the FDA had forced it to hold all shipments of Tablo for use in the home until Tablo received proper regulatory clearance. During a “Business Update” conference call held that day with analysts, Outset Medical CEO Leslie Trigg acknowledged the “ship hold” had already been in place for weeks before investors were provided this material information. Importantly, CEO Trigg disclosed for the first time that, rather than conducting studies using “real-world data” gathered in the “home environment” as Outset Medical previously stated was required by the FDA, in reality, Outset Medical had “run with a protocol that involves a simulated use environment at a human factors lab.” On this news, the price of Outset Medical stock fell an additional 34%, further damaging investors who suffered losses in Outset Medical stock.

Outset Medical Shareholders Urged to Call the Firm

If you purchased Outset Medical securities, have information, or have any questions concerning this announcement or your rights or interests with respect to these matters, please [click here](#) for more information or contact Timothy L. Miles, Esquire, at 615-587-7384, Toll-Free at 855-846-6529, or by email to tmiles@timmileslaw.com. If you inquire by email please include your mailing address, telephone number, and the number shares owned.

About Timothy L. Miles

Timothy L. Miles is a nationally recognized shareholder rights attorney raised in Nashville, Tennessee. Mr. Miles was recently selected by Martindale-Hubbell® and ALM as a 2022 Top Ranked Lawyer and a 2022 Top Rated Litigator. Mr. Miles also maintains the AV Preeminent Rating by Martindale-Hubbell®, their highest rating for both legal ability and ethics. Mr. Miles is a member of the prestigious Top 100 Civil Plaintiff Trial Lawyers: The National Trial Lawyers



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Timothy L. Miles, a nationally recognized shareholder rights attorney

Association, a superb rated attorney by Avvo, a recipient of the Lifetime Achievement Award by Premier Lawyers of America (2019) and recognized as a Distinguished Lawyer, Recognizing Excellence in Securities Law, by Lawyers of Distinction (2019). Awards: Top Rated Litigator by Martindale-Hubbell® and ALM (2019); 2019 Elite Lawyer of The South by Martindale-Hubbell® and ALM (2019); Member of the Top 100 Civil Plaintiff Trial Lawyers: The National Trial Lawyers Association (2017-2019); AV® Preeminent™ Rating by Martindale-Hubbell® (2014-2020); PRR AV Preeminent Rating on Lawyers.com (2017 & 2019); The Top-Rated Lawyer in Litigation™ for Ethical Standards and Legal Ability (Martindale-Hubbell® 2015); Lifetime Achievement Award by Premier Lawyers of America (2019); Superb Rated Attorney (Avvo); Avvo Top Rated Lawyer for (Avvo 2017-2020). Mr. Miles has authored numerous publications advocating for shareholdings including most recently: Free Portfolio Monitoring Services Offered by Plaintiff Securities Firms Provides Significant Benefits To Investors (Timothy L. Miles, Dec. 3, 2019).

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