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): September 24, 2020

Aerie Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-36152**	**20-3109565**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

4301 Emperor Boulevard, Suite 400
Durham, North Carolina 27703
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (919) 237-5300

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
Shares of common stock, par value $0.001 per share	**AERI**	**Nasdaq Global Market**

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 7.01. Regulation FD Disclosure.

On September 24, 2020, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing successful interim 90-day topline data from its six-month Phase 3b clinical trial in Europe known as Mercury 3, comparing Roclanda® to Ganfort®. A copy of this press release is furnished as Exhibit 99.1 hereto and is hereby incorporated by reference into this Item 7.01.

The information in this Item 7.01 (including Exhibit 99.1) is being furnished, not filed, pursuant to Regulation FD. Accordingly, the information in this Item 7.01 will not be incorporated by reference into any registration statement filed by the Company under the Securities Act of 1933, as amended, unless specifically identified therein as being incorporated therein by reference. The furnishing of the information in this Item 7.01 is not intended to, and does not, constitute a determination or admission by the Company that this information is material or complete, or that investors should consider this information before making an investment decision with respect to any security of the Company.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit relating to Item 7.01 shall be deemed to be furnished, and not filed:

99.1	Press Release dated September 24, 2020.
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 hereunto duly authorized.

AERIE PHARMACEUTICALS, INC.

Date: September 24, 2020

By: /s/ Richard J. Rubino
Richard J. Rubino
Chief Financial Officer

Exhibit 99.1

Aerie Pharmaceuticals Announces Successful Interim 90-Day Topline Data from its Six-Month Mercury 3 Clinical Trial in Europe

- Roclanda® Achieves Non-Inferiority to Ganfort® -

- Mercury 3 Performance Exceeds Prior Phase 3 Trials -

Durham, N.C., September 24, 2020 – Aerie Pharmaceuticals, Inc. (NASDAQ: AERI), an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, ocular surface diseases and retinal diseases, today announced successful interim 90-day topline data from its six-month Phase 3b clinical trial in Europe known as Mercury 3, comparing Roclanda® to Ganfort®.

Roclanda® is marketed in the United States as Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%. Ganfort® is approved for use in Europe but is not approved for use in the United States.

Mercury 3 was designed as a non-inferiority trial to compare intraocular pressure (IOP) reduction in patients with open-angle glaucoma or ocular hypertension.

Interim 90-Day Topline Highlights:

- Roclanda® met the overall trial objective by demonstrating non-inferiority to Ganfort® across nine of nine timepoints over 90 days.
- Roclanda® demonstrated consistent IOP reduction throughout the day of approximately 9.5 millimeters of mercury (mmHg) for an average reduction from baseline IOPs of approximately 37 percent.
- The IOP reductions observed in Mercury 3 exceeded those from both Mercury 1 and Mercury 2.
- The IOP reduction results for Roclanda® were highly consistent with those of Ganfort®.
- Incidence of ocular adverse events for Roclanda® were lower than observed in Mercury 1 and Mercury 2.
- Six-month topline results are expected by early 2021.

“We are pleased to have another set of clinical trial data that yet again reinforces the excellent efficacy profile of Rocklatan®. As background, Mercury 3 is not necessary for regulatory approval in Europe but rather is intended to elucidate its pricing and commercialization prospects in that region,” said Vicente Anido Jr., Ph.D., Chairman and Chief Executive Officer at Aerie.

Dr. Anido continued, “We believe these interim topline results point to consistent pricing levels for the two comparators in the trial. While we expect to receive approval for Roclanda® by early next year, we will wait for further clarity on U.S. pricing ramifications before determining the nature and timing of launch plans in Europe.”

About the Mercury 3 Clinical Trial and Comparators

Mercury 3 was designed as a non-inferiority trial to compare intraocular pressure (IOP) reduction in patients with open angle glaucoma or ocular hypertension. Approximately 430 subjects satisfying inclusion criteria were randomized to one of two arms and received masked study medication once-daily in the evening.

The Mercury 3 clinical trial included Roclanda®, which in the United States is marketed as Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% and represents a fixed-dose combination of Rhopressa® (netarsudil ophthalmic solution) 0.02% and prostaglandin analog latanoprost. Ganfort® represented the comparator, a fixed-dose combination of prostaglandin analog Lumigan® and beta blocker timolol.

Rocklatan® is the only fixed-dose combination product commercially available in the United States that includes a prostaglandin analog. The Ganfort® fixed-dose combination includes a prostaglandin analog and a beta blocker, and while it is approved for use in Europe, it is not approved for use in the United States.

About Rocklatan® (named Roclanda® in Europe)

Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% is a once-daily eye drop that is a fixed-dose combination of latanoprost, the most widely-prescribed prostaglandin analog (PGA), and netarsudil, the active ingredient in Rhopressa® (netarsudil ophthalmic solution) 0.02%, a first-in-class Rho kinase (ROCK) inhibitor specifically designed to target the trabecular meshwork (the eye’s principal drainage pathway). The diseased trabecular meshwork is considered to be the main cause of elevated intraocular pressure (IOP) in open-angle glaucoma and ocular hypertension. Rhopressa® works by restoring outflow through the trabecular meshwork, while latanoprost increases fluid outflow through a secondary mechanism known as the uveoscleral pathway. In clinical trials of Rocklatan®, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rocklatan®, including the product label, is available at www.rocklatan.com.

About Aerie Pharmaceuticals, Inc.

Aerie is an ophthalmic pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with open-angle glaucoma, ocular surface diseases and retinal diseases. Aerie’s first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, a once-daily eye drop approved by the U.S. Food and Drug Administration (FDA) for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular

hypertension, was launched in the United States in April 2018. In clinical trials of Rhopressa®, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rhopressa®, including the product label, is available at www.rhopressa.com. Aerie's second product for the reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension, Rocklatan® (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005%, the first and only fixed-dose combination of Rhopressa® and the widely-prescribed PGA (prostaglandin analog) latanoprost, was launched in the United States in May 2019. In clinical trials of Rocklatan®, the most common adverse reactions were conjunctival hyperemia, corneal verticillata, instillation site pain, and conjunctival hemorrhage. More information about Rocklatan®, including the product label, is available at www.rocklatan.com. Aerie continues to focus on global expansion and the development of additional product candidates and technologies in ophthalmology, including for wet age-related macular degeneration and diabetic macular edema. More information is available at www.aeriepharma.com.

Forward-Looking Statements

This press release contains forward-looking statements for purposes of the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. We may, in some cases, use terms such as "predicts," "believes," "potential," "proposed," "continue," "estimates," "anticipates," "expects," "plans," "intends," "may," "could," "might," "will," "should," "exploring," "pursuing" or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. Forward-looking statements in this release include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the duration and severity of the coronavirus disease (COVID-19) outbreak, including the impact on our clinical and commercial operations, demand for our products and financial results and condition of our global supply chains; our expectations regarding the commercialization and manufacturing of Rhopressa®, Rocklatan®, Rhokiinsa® and Roclanda® or any current or future product candidates, including the timing, cost or other aspects of their commercial launch; our commercialization, marketing, manufacturing and supply management capabilities and strategies in and outside of the United States; the success, timing, pricing and cost of our ongoing and anticipated preclinical studies and clinical trials for Rhopressa® and Rocklatan®, with respect to regulatory approval outside of the United States, and any current or future product candidates, including statements regarding the timing of initiation and completion of the studies and trials, such as statements in this press release regarding our expectations regarding the effectiveness of Rhopressa®, Rocklatan®, Rhokiinsa®, Roclanda® or any current or future product candidates; the timing of and our ability to request, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, as applicable, Rhopressa®, Rocklatan® or any current or future product candidates, including the expected timing of, and timing of regulatory and/or other review of, filings for, as applicable, Rhopressa®, Rocklatan® or any current or future product candidates; the potential advantages of Rhopressa® and Rocklatan® or any current or future product candidates; our plans to pursue development of additional product candidates and technologies; our ability to protect our proprietary technology and enforce our intellectual property rights; and our expectations regarding strategic operations, including our ability to in-license or acquire additional ophthalmic products, product candidates or technologies. In particular, the topline data presented herein is preliminary and based solely on information available to us as of the date of this press release and additional information about the results may be disclosed at any time. Additionally, FDA approval of Rhopressa® and Rocklatan® and EMA approval of Rhokiinsa® do not constitute regulatory approval of Rhopressa® and Rocklatan® in other jurisdictions, including EMA approval of Roclanda®, and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in such other jurisdictions, including EMA approval of Roclanda®. In addition, FDA approval of Rhopressa® and Rocklatan® do not constitute FDA approval of our current or any future product candidates, and there can be no assurance that we will receive FDA approval for our current or any future product candidates. Furthermore, EMA acceptance of the MAA for Roclanda® does not constitute EMA approval of Roclanda®, and there can be no assurance that we will receive EMA approval of Roclanda®. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics, industry change and other factors beyond our control, and depend on regulatory approvals and economic and other environmental circumstances that may or may not occur in the future or may occur on longer or shorter timelines than anticipated. We discuss many of these risks in greater detail under the heading "Risk Factors" in the quarterly and annual reports that we file with the Securities and Exchange Commission (SEC). Forward-looking statements are not guarantees of future performance and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this press release. Any forward-looking statements that we make in this press release speak only as of the date of this press release. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise, after the date of this press release.

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