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): November 5, 2019

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 November 5, 2019, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release reporting positive topline results for the Company's Phase 2 clinical trial evaluating netarsudil ophthalmic solution in Japanese patients. Netarsudil is a Rho kinase (ROCK) inhibitor specifically designed to increase outflow of aqueous humor through the trabecular meshwork, the eye's primary drainage pathway. Netarsudil ophthalmic solution 0.02% is known by the name Rhopressa® in the United States and is approved for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. It is also under regulatory review in the European Union, where it is called Rhokiinsa®. 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 November 5, 2019.
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: November 5, 2019

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

Exhibit 99.1

Aerie Pharmaceuticals Announces Positive Topline Results for Netarsudil Ophthalmic Solution in Phase 2 Study Conducted in Japan

Durham, NC, November 5, 2019 — (BUSINESS WIRE)— 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, retinal diseases and other diseases of the eye today reported positive topline results for the Company's Phase 2 clinical trial evaluating netarsudil ophthalmic solution in Japanese patients. Netarsudil is a Rho kinase (ROCK) inhibitor specifically designed to increase outflow of aqueous humor through the trabecular meshwork, the eye's primary drainage pathway. Netarsudil ophthalmic solution 0.02% is known by the name Rhopressa® in the United States and is approved for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. It is also under regulatory review in the European Union, where it is called Rhokiinsa®.

Netarsudil Ophthalmic Solution Phase 2 Highlights

- The objective of the 28-day Phase 2 study was to evaluate the intraocular pressure (IOP)-reducing effect and safety of three concentrations of netarsudil ophthalmic solution (0.01%, 0.02% and 0.04%) compared to placebo in subjects with open-angle glaucoma or ocular hypertension. All treatments were administered once daily in the evening.
- The study was designed in accordance with the requirements of Japan's Pharmaceuticals and Medical Devices Agency (PMDA) as a precursor to Phase 3 trials to support potential regulatory submission of netarsudil ophthalmic solution in Japan. The primary efficacy endpoint was mean diurnal IOP on Day 29.
- The baseline IOPs tested in the study ranged from 15 to less than 35 millimeters of mercury (mmHg) for patients with open-angle glaucoma, and from 22 to less than 35 mmHg for patients with ocular hypertension. Previous studies have shown that the average IOP, as observed in Japan, is approximately 3 mmHg lower than as observed in the United States.
- A total of 215 randomized subjects were included, with between 51 and 55 subjects in each arm. Average baseline IOPs ranged from 20.3 mmHg to 21.1 mmHg across the four arms. A total of 207 patients completed the study.
- Mean diurnal IOP at Day 29 was statistically significantly lower in subjects treated with each of the netarsudil concentrations than those treated with placebo, with all P values <0.0001.
- The netarsudil ophthalmic solution 0.01% concentration reduced mean diurnal IOP by a range of 4.1 to 4.6 mmHg, the 0.02% concentration reduced mean diurnal IOP by a range of 4.4 to 4.8 mmHg, and the 0.04% concentration reduced mean diurnal IOP by a range of 4.8 to 5.1 mmHg. The placebo arm reduced mean diurnal IOP by a range of 1.4 to 1.7 mmHg. The ranges reflect IOP measurements taken at week 1, week 2 and week 4. IOP lowering was consistent across the measurement period.

- The most common adverse event was conjunctival hyperemia, which when measured by biomicroscopy, was observed in 23.6 percent of subjects in the netarsudil 0.01% arm, 37.0 percent of subjects in the netarsudil 0.02% arm, 56.9 percent of subjects in the netarsudil 0.04% arm, and 1.8 percent in the placebo arm. The level of conjunctival hyperemia observed in the netarsudil 0.02% arm was notably less than levels observed in the clinical trials for Rhopressa® previously conducted in the United States. The large majority of the conjunctival hyperemia was considered mild. There were no serious adverse events.
- These topline results will be discussed in greater detail on Aerie's third-quarter financial results call scheduled for November 6, 2019 at 5 p.m. ET, and a corresponding slide presentation will be made available at http://investors.aeriepharma.com approximately one hour before the call.

"The topline results of this large Phase 2 study confirm that netarsudil ophthalmic solution maintains strongIOP-lowering efficacy in a patient population with lower baseline pressures, a clinical need that remains unmet by currently available glaucoma therapeutics in Japan, the United States and in Europe" said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie. "These findings, which will be presented in full at an upcoming ophthalmic congress, also suggest that the concentration of netarsudil that provides the best balance of efficacy and tolerability in this population is 0.02%, which is the concentration for Rhopressa® currently marketed in the United States. We will now look to meet with Japan's Pharmaceutical and Medical Devices Agency to discuss these results and identify next steps for a Phase 3 program in Japan. With this data in hand we are advancing a number of different activities, including potential partnering discussions, to gain approval and ultimately commercialize our products in Japan."

About Aerie Pharmaceuticals, Inc.

Aerie is an ophthalmic pharmaceutical company focused on the discovery, development and commercialization offirst-in-class therapies for the treatment of patients with open-angle glaucoma, retinal diseases and other diseases of the eye. 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 U.S. 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 intraocular pressure 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, has been approved by the FDA and is now available in the United States. In U.S. 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 include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: our expectations regarding the commercialization and manufacturing of Rhopressa® and Rocklatan® or any current or future product candidates, including the timing, cost or other aspects of the commercial launch of Rhopressa® and Rocklatan® or any current or future product candidates; our commercialization, marketing, manufacturing and supply management capabilities and strategies in and outside of the United States; the success, timing 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 or additional indications, and any current or future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the effectiveness of Rhopressa®, Rocklatan® 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 within and beyond ophthalmology; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma, including development of our retina program; 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, FDA approval of Rhopressa® and Rocklatan® do not constitute regulatory approval of Rhopressa® and Rocklatan® in jurisdictions outside of the United States and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan® in jurisdictions outside of the United States. 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.

Contacts

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