
**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): March 12, 2019

Aerie Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation)

001-36152
(Commission
File Number)

20-3109565
(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 (*see* General Instruction A.2. below):

- 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))

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 March 12, 2019, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing that the U.S. Food and Drug Administration has approved Rocklatan™ (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% to reduce elevated intraocular pressure in patients with open-angle glaucoma or ocular hypertension. 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 March 12, 2019.

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated March 12, 2019.

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: March 12, 2019

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

Aerie Pharmaceuticals Announces U.S. FDA Approval of Rocklatan™ (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% for the Reduction of Intraocular Pressure in Patients with Open-Angle Glaucoma or Ocular Hypertension

– First and Only Once-Daily, Fixed-Dose Combination of a Prostaglandin Analog and a Rho Kinase (ROCK) Inhibitor –

– Rocklatan™ Demonstrated Statistical Superiority over Widely-Prescribed First-Line Agent Latanoprost –

Durham, N.C. — (BUSINESS WIRE) — Aerie Pharmaceuticals, Inc. (NASDAQ:AERI) (Aerie or the Company), 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 announced that the U.S. Food and Drug Administration (FDA) has approved Rocklatan™ (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% to reduce elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. A link to the full product label is available on the Aerie website at <http://investors.aeriepharma.com>.

Rocklatan™ 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 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.

Aerie launched Rhopressa® in the United States in April 2018. The Company plans to launch Rocklatan™ in the United States in the second quarter of 2019.

“We are in the unique position of receiving FDA approval on a second glaucoma treatment less than a year from the U.S. launch of Rhopressa®,” said Vicente Anido, Jr., Ph.D., chairman and chief executive officer at Aerie. “Together, Rocklatan™ and Rhopressa® give us a broad therapeutic franchise, based on our ROCK inhibitor netarsudil, that addresses many of the needs of clinicians and patients in a wide variety of treatment settings. Our existing salesforce, which has been calling on U.S. eye-care professionals since last May, is very well positioned to introduce Rocklatan™ to these doctors and help them understand the clinical utility of both products in the care of their patients with glaucoma. We have also been working diligently on securing favorable reimbursement for our products, with Rhopressa® now enjoying broad commercial and Medicare Part D coverage, and Rocklatan™ already under review by major payers.”

The FDA approval of Rocklatan™ is based on data from two Phase 3 registration trials, MERCURY 1 and MERCURY 2. In these studies, Rocklatan™ achieved its primary 90-day efficacy endpoint as well as positive 12-month safety and efficacy results, demonstrating statistically superior IOP reduction over latanoprost and netarsudil at every measured time point. More than 60% of patients taking Rocklatan™ in the two MERCURY studies achieved an IOP reduction of 30% or more, a frequency that was nearly twice that achieved by participants taking latanoprost alone. Rocklatan™ also helped more patients get to low target pressures. Nearly twice as many patients taking Rocklatan™ reached 16 mmHg or lower and nearly three times as many reached 14 mmHg or lower compared to latanoprost.

In the two MERCURY studies, Rocklatan™ treatment was associated with generally mild and tolerable ocular adverse events, with minimal systemic side effects. The most common ocular adverse event in controlled clinical studies with Rocklatan™ was conjunctival hyperemia. Ninety percent of patients who experienced hyperemia reported it as mild and 5% discontinued because of it. Other common ocular adverse effects reported in the studies include instillation site pain, corneal verticillata and conjunctival hemorrhage.

About Rocklatan™

Indications and Usage

ROCKLATAN™ (netarsudil and latanoprost ophthalmic solution) 0.02%/0.005% is indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension.

Select Important Safety Information

Although not observed in the two MERCURY studies, latanoprost has been reported to cause changes to pigmented tissues, including pigmentation of the iris, periorbital tissue (eyelid) and eyelashes. Iris pigmentation is likely to be permanent. Latanoprost has also been associated with gradual changes to eyelashes including increased length, thickness and number of lashes. These changes are usually reversible.

About Glaucoma

Glaucoma is a disease that causes damage to the optic nerve. It is characterized by progressive degeneration of retinal cells, resulting in irreversible vision loss and, potentially, blindness. At least 60 million people worldwide are thought to be affected. The National Eye Institute estimates that more than 2.7 million people in the United States suffer from glaucoma, a number expected to reach 4.3 million by 2030. Furthermore, The Eye Diseases Prevalence Research Group has estimated that only half of Americans with glaucoma know they have the disease. As a result, glaucoma remains a leading cause of adult blindness but, with diagnosis and effective treatment, is also one of the most preventable.

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, retinal diseases and other diseases of the eye. Aerie's first product, Rhopressa® (netarsudil ophthalmic solution) 0.02%, a once-daily eyedrop 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, 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 expected to be launched in the United States in the second quarter of 2019. 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 future product candidates, including the timing, cost or other aspects of the commercial launch of Rhopressa® and Rocklatan™ or any future product candidates; our commercialization, marketing, manufacturing and supply management capabilities and strategies; 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 future product candidates, including statements regarding the timing of initiation and completion of the studies and trials; 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 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 future product candidates; the potential advantages of Rhopressa® and Rocklatan™ or any 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. 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). In particular, FDA approval of Rhopressa® and Rocklatan™ do not constitute FDA approval of AR-1105, AR-13503 or any future product candidates, and there can be no assurance that we will receive FDA approval for AR-1105, AR-13503 or any future product candidates. FDA approval of Rhopressa® and Rocklatan™ also do not constitute regulatory approval of Rhopressa® and Rocklatan™ in jurisdictions outside the United States and there can be no assurance that we will receive regulatory approval for Rhopressa® and Rocklatan™ in jurisdictions outside the United States. 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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