
**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 18, 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 18, 2019, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing the commencement of patient dosing in a Phase 2 clinical trial of AR-1105, its investigational dexamethasone intravitreal implant, in patients with macular edema due to retinal vein occlusion. 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 18, 2019.

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated March 18, 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 18, 2019

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

**Aerie Pharmaceuticals Initiates Phase 2 Clinical Trial of AR-1105 (Dexamethasone
Intravitreal Implant) in Patients with Macular Edema Associated with Retinal Vein Occlusion**

DURHAM, N.C. – (BUSINESS WIRE) — Aerie Pharmaceuticals, Inc. (NASDAQ:AERI) (Aerie), 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 the commencement of patient dosing in a Phase 2 clinical trial of AR-1105, its investigational dexamethasone intravitreal implant, in patients with macular edema due to retinal vein occlusion (RVO).

This Phase 2 study (AR1105-CS201) will be conducted at approximately 20 centers in the United States and enroll up to 45 patients. The primary objectives of the trial are to evaluate the safety, tolerability and efficacy of the AR-1105 dexamethasone intravitreal implant. The study will be conducted in two stages. In the initial safety stage, up to 5 patients will be enrolled in a single cohort to receive clinical formulation #1 (CF-1), delivering a 340µg dose of dexamethasone in a single intravitreal injection. In Stage 2, up to 40 patients will be randomized 1:1 to receive either CF-1 or a second clinical formulation, CF-2, which delivers the same dose of dexamethasone over a longer period. Safety and efficacy will be evaluated at six months. More information about the study is available at www.clinicaltrials.gov under the study designation NCT 03739593.

“This is a proof of concept study for AR-1105 and for the retina portfolio we are building based on two enabling technologies, the bio-erodible polymers we are developing with DSM and our PRINT® manufacturing platform,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer. “The results of this trial should allow us to optimize the formulation of AR-1105 to achieve this clinical objective in Phase 3 studies. By the end of this quarter, we also plan to file an Investigational New Drug (IND) application for our second sustained delivery retina product, AR-13503 Implant, a bio-erodible implant delivering a Rho kinase/Protein kinase C inhibitor for the treatment of wet age-related macular degeneration and diabetic macular edema.”

About AR-1105

AR-1105 is a bio-erodible implant that is designed to steadily release the steroid dexamethasone over a six-month period. It is administered by intravitreal injection, a commonly-used, in-office treatment method. In addition to its six-month duration of effect, the potential benefits of AR-1105 compared to other intravitreal steroid products include improved administration with a smaller 25G needle and the potential for fewer adverse events due to lower peak drug levels. The market for retinal disease therapeutics in the United States, which is dominated by anti-VEGF agents, was approximately \$6 billion in 2018. The intravitreal steroid segment represented approximately \$200 million of that total.

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 for the reduction of elevated intraocular pressure (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, has been approved by the FDA and is expected to be launched in the United States in the second quarter of 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 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; such as statements in this press release regarding any expected clinical trials for AR-1105 or AR-13503 and results of such clinical 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.

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