AERIE PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

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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 1, 2017

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)**

2030 Main Street, Suite 1500
Irvine, California 92614
(Address of principal executive offices) (Zip code)

Registrant's telephone number, including area code: (949) 526-8700

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))

Item 7.01. Regulation FD Disclosure.

On March 1, 2017, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing the resubmission of the Company's New Drug Application for Rhopressa ™ (netarsudil ophthalmic solution) 0.02% with the U.S. Food and Drug Administration. A copy of the 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 1, 2017.

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 1, 2017

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

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated March 1, 2017.

Exhibit 99.1

Aerie Pharmaceuticals Announces Resubmission of NDA for Rhopressa ™ (netarsudil ophthalmic solution) 0.02%

IRVINE, Calif., March 1, 2017 — (BUSINESS WIRE)— Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of glaucoma and other diseases of the eye, today announced that on February 28, 2017 it resubmitted its NDA (New Drug Application) for Rhopressa ™ to the FDA after notification by its contract drug product manufacturer that the vendor's Tampa, Florida facility is now ready for pre-approval inspection by the FDA for Rhopressa ™ . As background, the Rhopressa ™ NDA was withdrawn in October 2016 due to the contract manufacturer not yet being prepared for pre-approval inspection by the FDA at that time.

"We are delighted to have our Rhopressa ™ NDA filing back on track, and we expect a standard twelve-month FDA review process from the date of resubmission. Pending approval, we anticipate product launch in the second quarter of 2018," said Vicente Anido, Jr., Ph.D., Chief Executive Officer and Chairman at Aerie.

Dr. Anido added, "Looking forward to additional upcoming milestones, we continue to expect in the second quarter of 2017, the readout of the six-month safety and efficacy data for the Rhopressa ™ Phase 3 registration trial, known as Rocket 4. We also anticipate in the second quarter of 2017, the readout of the 90-day efficacy data from Mercury 2, our second Phase 3 registration trial for Roclatan ™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%."

About Rhopressa™

Rhopressa ™ (netarsudil ophthalmic solution) 0.02%, is a novel eye drop that we believe, if approved, would become the only once-daily product available that, based on Aerie's preclinical and clinical studies, specifically targets the trabecular meshwork, the eye's primary fluid drain and the diseased tissue responsible for elevated intraocular pressure (IOP) in glaucoma. Preclinical and clinical studies have also demonstrated that Rhopressa ™ lowers episcleral venous pressure, which contributes approximately half of IOP in healthy subjects. Further, based on Aerie's preclinical studies, Rhopressa ™ may provide an additional mechanism that reduces fluid production in the eye and therefore lowers IOP. Biochemically, the active ingredient in Rhopressa ™ , netarsudil, has been shown in Aerie studies to inhibit both Rho Kinase (ROCK) and norepinephrine transporter (NET). Recent preclinical studies have also shown that Rhopressa ™ may have disease-modifying properties, including an anti-fibrotic effect of netarsudil on trabecular meshwork cells and the potential to increase perfusion of the trabecular meshwork.

The results of two Phase 3 registration trials (Rocket 2 and Rocket 1) for Rhopressa ™ were included in the NDA filing resubmitted to the FDA, as announced today. Rocket 2 will represent the pivotal trial, and Rocket 1 will be supportive. There are two additional Phase 3 registration trials currently underway for Rhopressa ™ , named Rocket 3 and Rocket 4. Rocket 3 is a 12-month safety-only study in Canada that was not needed for the NDA filing. Rocket 4 is designed to provide adequate six-month safety data for

regulatory filing purposes in Europe, and was also not needed for the NDA filing. The 90-day efficacy results from Rocket 4 and Mercury 1, the initial Phase 3 registration trial for Aerie product candidate Roclatan ™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, were also included in the resubmitted Rhopressa ™ NDA filing as supportive.

About Aerie Pharmaceuticals, Inc.

Aerie is a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of first-in-class therapies for the treatment of patients with glaucoma and other diseases of the eye. Aerie's two lead product candidates are once-daily IOP-lowering therapies with novel mechanisms of action to treat patients with glaucoma or ocular hypertension. The NDA filing for Rhopressa ™ (netarsudil ophthalmic solution) 0.02% was resubmitted in February 2017. The Company's second product candidate, Roclatan ™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%, which is a fixed dose combination of Rhopressa ™ and widely prescribed PGA latanoprost, currently has two Phase 3 registration trials underway, named Mercury 1 and Mercury 2. If these trials are successful, a Roclatan ™ NDA filing is expected to take place in late 2017 or early 2018. Aerie is also focused on the development of additional product candidates and technologies in ophthalmology.

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: the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for our current product candidates, including statements regarding the timing of initiation and completion of the studies and trials; our expectations regarding the clinical effectiveness of our product candidates and results of our clinical trials; the timing of and our ability to obtain and maintain U.S. Food and Drug Administration or other regulatory authority approval of, or other action with respect to, our product candidates; our expectations regarding the commercialization of our product candidates; the potential advantages of our product candidates; our plans to pursue development of our product candidates for additional indications and other therapeutic opportunities; our plans to explore possible uses of our existing proprietary compounds beyond glaucoma; 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 or product candidates. By their nature, forward-looking statements involve risks and uncertainties because they relate to events, competitive dynamics and industry change, and depend on regulatory approvals and economic 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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