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): April 25, 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 (*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 April 25, 2019, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing the U.S. Food and Drug Administration has reviewed the Investigational New Drug Application for AR-13503, a novel multi-kinase (Rho kinase/Protein kinase C) inhibitor sustained-release implant and it is now in effect, allowing Aerie to initiate human studies in the treatment of neovascular age-related macular degeneration and diabetic macular edema. 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 April 25, 2019.

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated April 25, 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: April 25, 2019

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

Exhibit 99.1

Aerie Pharmaceuticals Announces Acceptance of Its Investigational New Drug Application for AR-13503 Sustained Release Implant

First-In-Human Clinical Study Will be Initiated Later in Second Quarter 2019

DURHAM, N.C.— (BUSINESS WIRE) — April 25, 2019 — 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 announced that the U.S. Food and Drug Administration (FDA) has reviewed the Investigational New Drug Application (IND) for AR-13503, a novel multi-kinase (Rho kinase/Protein kinase C (ROCK/PKC)) inhibitor sustained-release implant (the AR-13503 implant) and it is now in effect, allowing Aerie to initiate human studies in the treatment of neovascular age-related macular degeneration (nAMD) and diabetic macular edema (DME). The IND was submitted in March 2019. Aerie expects to initiate a first-in-human clinical study later in the second quarter of 2019.

The AR-13503 implant is a bio-erodible polyesteramide polymer implant that provides controlled release of AR-13503 over a sustained period. It is designed to be administered approximately once every six months by intravitreal injection. Preclinical studies suggest that AR-13503 has the potential to inhibit angiogenesis, preserve the blood retinal barrier, and reduce retinal fibrosis in retinal diseases such as nAMD and DME, while potentially reducing the treatment burden associated with more frequent intravitreal injections.

“While the standard-of-care anti-VEGF therapies are effective for many patients with nAMD and DME, there are many patients who do not respond adequately to these therapies or who lose their initial gains in vision over time. By targeting multiple disease processes that underlie progression in these common, sight-threatening retinal diseases, our research suggests that ROCK/PKC inhibitors such as AR-13503 may prove useful as alternative or additive therapies to the currently-available treatments,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer. “The AR-13503 implant marks our second foray into the retina space, with this product candidate leveraging both our scientific leadership in the creation of small-molecule kinase inhibitors for disease intervention along with our proprietary ophthalmic drug delivery platform.”

About Retinal Disease

The retina is a thin membrane lining the back of the eye composed of highly-specialized cells that convert visible light into electrical impulses that reach the brain through the optic nerve. There are a variety of diseases, including progressive disorders such as age-related macular degeneration (AMD) and diabetic macular edema (the macula is the central portion of the retina), that can damage the retina and cause visual impairment or permanent blindness. In the United States, AMD is the leading cause of significant visual acuity loss in people over age 50 and diabetic retinopathy is the most common cause of irreversible blindness among working-age

people. As a result, the retinal disease market is the largest therapeutic category in ophthalmology, with revenues in the United States reaching approximately $6.0 billion in 2018. Because current medical therapies are not adequately effective for many patients and do not stop disease progression, new treatment options are needed.

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 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 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; 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 such as AR-13503 or AR-1105, 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 such as AR-13503 or AR-1105; the potential advantages of Rhopressa® and Rocklatan® or any future product candidates such as AR-13503 or AR-1105; 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. FDA approval of Rhopressa® and Rocklatan® 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. In addition, the acceptance of the IND discussed in this press release does not constitute FDA approval of AR-13503 and the outcome of later clinical trials for AR-13503 may not be sufficient to submit an NDA with the FDA or to receive FDA approval. 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.

Source: Aerie Pharmaceuticals, Inc.

Media: Tad Heitmann 949-526-8747; theitmann@aeriepharma.com
Investors: Ami Bavishi 908-947-3949; abavishi@aeriepharma.com