

AERIE PHARMACEUTICALS INC

FORM 8-K (Current report filing)

Filed 07/31/17 for the Period Ending 07/31/17

Address	7020 KIT CREEK ROAD SUITE 270 RESEARCH TRIANGLE PARK, NC 27709
Telephone	919-313-9650
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Symbol	AERI
SIC Code	2836 - Biological Products, Except Diagnostic Substances
Industry	Biotechnology & Medical Research
Sector	Healthcare
Fiscal Year	12/31

**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): July 31, 2017

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)

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))

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 July 31, 2017, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing a collaboration agreement with DSM. 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 July 31, 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: July 31, 2017

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

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Press Release dated July 31, 2017.

Aerie Pharmaceuticals Enters into Collaboration Agreement with DSM Focused on Technology to Potentially Deliver Aerie Compounds to Treat Retinal Diseases such as Wet AMD

IRVINE, Calif., July 31, 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 patients with glaucoma and other diseases of the eye, today announced that it has entered into a collaborative research, development and license agreement with DSM.

The research collaboration agreement includes an option to license DSM's bioerodible polymer implant technology for evaluating its application to the delivery of certain Aerie compounds, initially focused on retinal diseases. DSM's technology uses polyesteramide polymers (PEA) to produce an injectable, thin fiber that is minute in size. Preclinical experiments have demonstrated early success in conjunction with Aerie compounds, including demonstration of linear sustained elution rates over several months and achievement of target retinal drug concentrations.

Aerie previously reported data on Aerie-owned small molecule preclinical product candidate AR-13154, which inhibits Rho kinase and Protein kinase C and thus addresses vascular dysfunction, fibrosis, and inflammation. This molecule has generated lesion size decreases in a preclinical model of wet AMD (age-related macular degeneration) at levels similar to the market-leading wet AMD anti-VEGF product, and has generated meaningful incremental lesion size reduction when added adjunctively to the anti-VEGF product. Preclinical studies also demonstrated the promising potential of this molecule to reduce neovascularization in a model of proliferative diabetic retinopathy. Pending additional studies, AR-13154 and related compounds may have the potential to provide an entirely new mechanism and pathway to treat these diseases.

"A key to unlocking the potential of AR-13154 and related Aerie-owned compounds for the treatment of retinal diseases is the identification of the appropriate technology to achieve longer-term sustained delivery of our small molecules to the back of the eye. We are hopeful that DSM's PEA technology may prove to be that technology," said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie.

The terms of the agreement with DSM were not disclosed and the agreement is immaterial to Aerie based on the level of current financial commitments.

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 current product candidates are once-daily intraocular pressure lowering therapies with novel mechanisms of action to treat patients with glaucoma or ocular hypertension. The NDA (new drug application) for Rhopressa™ (netarsudil ophthalmic solution) 0.02% was submitted to the U.S. Food and Drug Administration (FDA) in February 2017, and, in May 2017, the FDA set the

PDUFA (Prescription Drug User Fee Act) goal date for the completion of the FDA's review of the Rhopressa™ NDA for February 28, 2018. Aerie'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, achieved its primary efficacy endpoint in two Phase 3 registration trials, named Mercury 1 and Mercury 2, and also achieved successful 12-month safety and efficacy results in Mercury 1. The Roclatan™ NDA submission is expected to take place in the first half of 2018. Aerie is also focused on the development of additional product candidates and technologies in ophthalmology.

DSM - Bright Science. Brighter Living.™

Royal DSM is a global science-based company active in health, nutrition, and materials. By connecting its unique competences in life sciences and materials sciences DSM is driving economic prosperity, environmental progress, and social advances to create sustainable value for all stakeholders simultaneously. DSM delivers innovative solutions that nourish, protect, and improve performance in global markets such as food and dietary supplements, personal care, feed, medical devices, automotive, paints, electrical and electronics, life protection, alternative energy, and bio-based materials. DSM and its associated companies deliver annual net sales of about € 10 billion with approximately 25,000 employees. The company is listed on Euronext Amsterdam. More information can be found at www.dsm.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: the success, timing and cost of our ongoing and anticipated preclinical studies and clinical trials for our current and potential future 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 request, obtain and maintain FDA or other regulatory authority approval of, or other action with respect to, our product candidates, including the expected timing of, and timing of regulatory and/or other review of, filings for our product candidates; our expectations regarding the commercialization and manufacturing of our product candidates; the potential advantages of our product candidates; our plans to pursue development of additional product candidates and technologies in ophthalmology, including 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 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, the receipt of the PDUFA goal date notification does not constitute FDA approval of the Rhopressa™ NDA, and there can be no assurance that the FDA will complete its review by the PDUFA goal date, that the FDA will not require changes or additional data, whether as a result of recommendations, if any, made by any FDA advisory committee or otherwise, that must be made or received before it will approve the NDA, if ever, or that the FDA will approve the NDA. In addition, the preclinical research discussed in this press release is preliminary and the outcome of such preclinical studies may not be predictive of the outcome of later clinical trials. Any future clinical trial results may not demonstrate safety and efficacy sufficient to obtain regulatory approval related to the preclinical research findings discussed in this press release. 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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