
**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): September 19, 2018

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 or after September 19, 2018, representatives of Aerie Pharmaceuticals, Inc. (the “Company”) may present to various investors the information described in the slides attached to this report as Exhibit 99.1 hereto, which 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 Company Overview Presentation dated September 2018.

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Company Overview Presentation dated September 2018.



Company Overview

Ophthalmology Futures European Forum
Vienna, Austria

Presenter: Richard Rubino, Aerie Chief Financial Officer

September 20, 2018

Important Information



The information in this presentation does not contain all of the information that a potential investor should review before investing in Aerie shares. The descriptions of Aerie Pharmaceuticals, Inc. (the "Company" or "Aerie") in this presentation are qualified in their entirety by reference to reports filed with the SEC. Certain information in this presentation has been obtained from outside sources or anecdotal in nature. While such information is believed to be reliable for the purposes used herein, no representations are made as to the accuracy or completeness thereof and we take no responsibility for such information.

Any discussion of the potential use or expected success of Rhopressa® (netarsudil ophthalmic solution) 0.02%, with respect to foreign approval or additional indications, and our current or any future product candidates is subject to regulatory approval. In addition, any discussion of U.S. Food and Drug Administration ("FDA") approval of Rhopressa® does not guarantee successful commercialization of Rhopressa® or FDA approval of Roclatan™. For more information on Rhopressa®, including prescribing information, refer to the full Rhopressa® product label at www.rhopressa.com.

The information in this presentation is current only as of its date and may have changed or may change in the future. We undertake no obligation to update this information in light of new information, future events or otherwise. We are not making any representation or warranty that the information in this presentation is accurate or complete.

Certain statements in this presentation, including any guidance or timelines presented herein, are "forward-looking statements" within the meaning of the federal securities laws. Words such as "may," "will," "should," "would," "could," "believe," "expects," "anticipates," "plans," "intends," "estimates," "targets," "projects," "potential" or similar expressions are intended to identify these forward-looking statements. These statements are based on the Company's current plans and expectations. Known and unknown risks, uncertainties and other factors could cause actual results to differ materially from those contemplated by the statements. In evaluating these statements, you should specifically consider various factors that may cause our actual results to differ materially from any forward-looking statements. In particular, FDA approval of Rhopressa® does not constitute approval of Roclatan™, and there can be no assurance that we will receive FDA approval for Roclatan™ or any future product candidates. Any top line data presented herein is preliminary and based solely on information available to us as of the date of this presentation and additional information about the results may be disclosed at any time. In particular, FDA approval of Rhopressa® does not constitute FDA approval of Roclatan™, and there can be no assurance that we will receive FDA approval for Roclatan™ or any future product candidates. FDA approval of Rhopressa® also does not constitute regulatory approval of Rhopressa® in jurisdictions outside the United States and there can be no assurance that we will receive regulatory approval for Rhopressa® in jurisdictions outside the United States. Our receipt of a Prescription Drug User Fee Act ("PDUFA") goal date notification for Roclatan™ does not constitute FDA approval of the Roclatan™ New Drug Application ("NDA"), and there can be no assurance that the FDA will complete its review by the PDUFA goal date of March 14, 2019, that the FDA will not require changes or additional data 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 presentation is preliminary and the outcome of such preclinical studies may not be predictive of the outcome of later 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 presentation. These risks and uncertainties are described more fully in the quarterly and annual reports that we file with the SEC, particularly in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Such forward-looking statements only speak as of the date they are made. We undertake no obligation to publicly update or revise any forward-looking statements, whether because of new information, future events or otherwise, except as otherwise required by law.

Aerie IOP-Reducing Products (IP 2030+)

- **Rhopressa[®]** (netarsudil ophthalmic solution) 0.02%
 - *Successfully launched in U.S. April 30, 2018*
- **Roclatan[™]** (netarsudil / latanoprost ophthalmic solution) 0.02% / 0.005%
 - *U.S. NDA accepted, PDUFA set for March 14, 2019*
- **Globalization Plan Under Way** – Europe and Japan



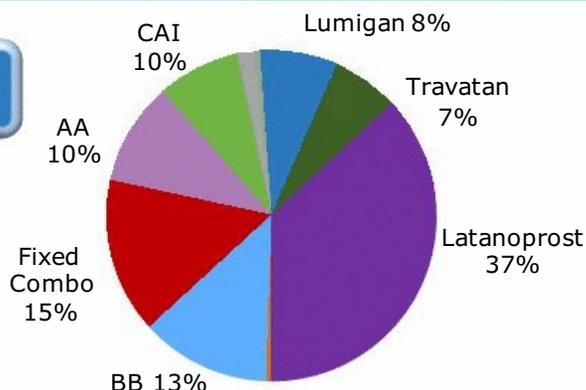
Pipeline Activities

- **Rhopressa[®]** – 24-hour IOP reduction, normal tension glaucoma, etc.
- **Retina Program** – AR-13503 and AR-1105 implants
- **Sustained Release / Implant Manufacturing Platform**
- **Beyond Ophthalmology** – potential for Aerie-owned molecules

Rhopressa[®]: Market Perspective

2017 U.S. Glaucoma Market

- ~\$3B Market, 37M TRx, 61M bottles
- Half of volume first-line (PGAs)
- Half of volume 2-3X/Day Adjuncts



Rhopressa[®]: HCP's Positioning as Concomitant Therapy

- New drug class per drug databases
- Once-daily dosing directed at site of pathology, the trabecular meshwork
- Consistent IOP reduction over 12 months and across all IOPs tested, as demonstrated in clinical trials

Refer to the full Rhopressa[®] product label at www.rhopressa.com.

Rhopressa[®] has not been approved by any regulatory authority other than the FDA.

GraphSourceIQVIATRx Data
 CAI: Carbonic Anhydrase Inhibitor
 AA: Alpha Agonist
 BB: Beta Blocker

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Rhopressa[®]: U.S. Commercialization Status



- Full Commercial Team on board
- Medical Affairs and Compliance Teams in place
- Adequate product in inventory and supply chain
- Market Access contracts with top Medicare Part D and Commercial Payers rapidly advancing
 - Covered Market is ~50/50 Commercial / Part D
 - Part D coverage generally commences January 2019; for those uncovered, prior authorization success rate for Rhopressa[®] of ~80%

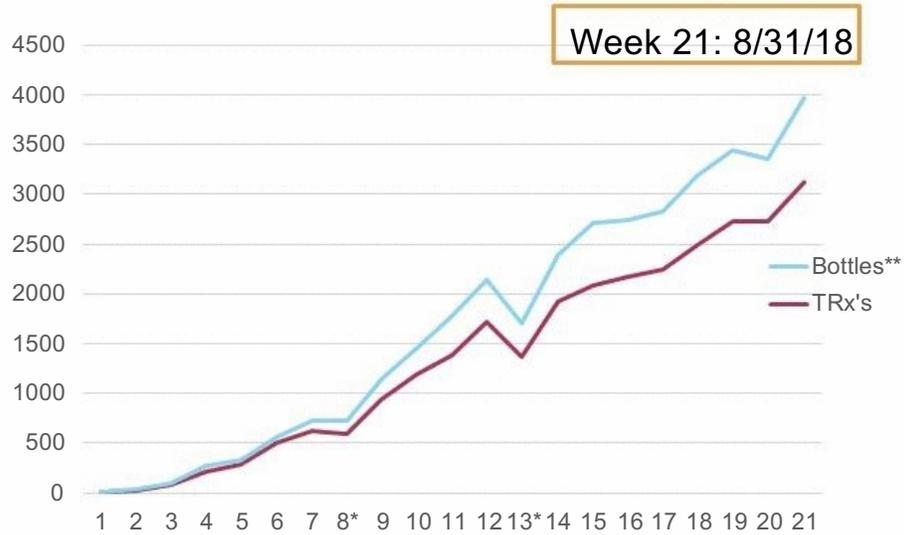
**~80% of Commercial lives covered:
~25% Tier 2 (preferred brand tier) + ~55% Tier 3**

**~12% of Medicare Part D lives already covered in Tier 2
More to come in early Q4**

Rhopressa® U.S. Launch Update



Weekly IQVIA Total Rx's and Extended Units:



*Holiday Weeks

**Actual bottles dispensed exceed TRx's due to extended supply plans (e.g., 90 days' supply)

Examples of Early Rhopressa® Feedback



Product Performance:

End-stage glaucoma patient at brink of needing surgery. Patient on maximal medical therapy (PGA/Combo/CAI) with IOP of 18 mmHg. Added Rhopressa® and IOP dropped to 13 mmHg, avoiding surgery.

Patient on maximal drug therapy and inadequately controlled at 16 mmHg, with patient requiring surgery as next step. Patient IOP reduced to 12 mmHg with Rhopressa® and surgery canceled.

Physician added Rhopressa® to a patient already on four medications, and Rhopressa® reduced IOP from 33 mmHg to 19 mmHg.

Physician's first experience with Rhopressa®, patient's IOP was cut in half from 30 mmHg to 15 mmHg.

Observations on file are anecdotal and not necessarily indicative of the entire population.
Rhopressa® has not been approved by any regulatory authority other than the FDA.

Roclatan™ Combination Product Candidate



Roclatan™ (netarsudil / latanoprost ophthalmic solution) 0.02% / 0.005%

Positioning as First Line Therapy:

- Benefits of Rhopressa® while also targeting the secondary drain
- Achieved statistical superiority to market-leading latanoprost
 - At each of nine time points in each of the two Phase 3 trials
- Potential to become the most efficacious IOP-reducing medication for glaucoma or ocular hypertension, if approved

PDUFA Date Set for March 14, 2019

Roclatan™ Efficacy and Safety



Efficacy:

- Roclatan™ demonstrated statistical superiority over its components (market-leading PGA latanoprost and Rhopressa®) in Mercury 1 and 2 Phase 3 trials, at all measured time points
- Consistent incremental IOP-reduction over latanoprost and Rhopressa® in the range of 1 to 3 mmHg

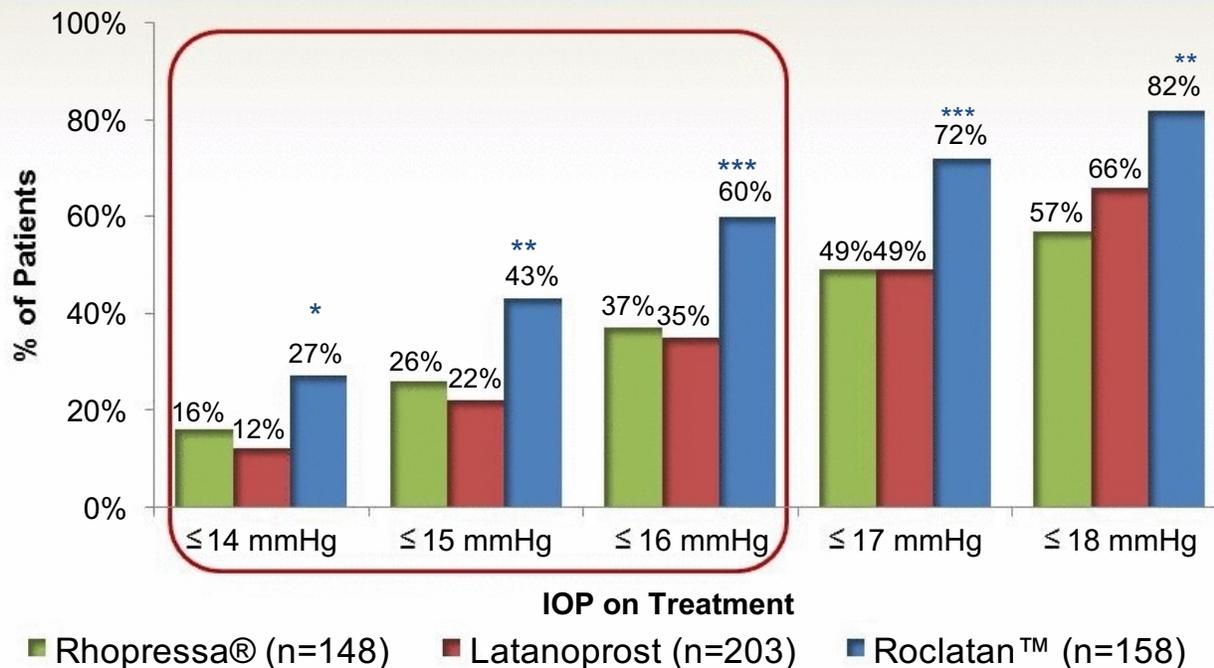
Safety:

- No treatment-related serious adverse events and minimal evidence of treatment-related systemic effects. The most common adverse event is conjunctival hyperemia with ~60% incidence, majority mild and sporadic and present in 20% of subjects at baseline
- Other ocular AEs occurring in ~5-15% of subjects receiving Roclatan™ included: cornea verticillata, conjunctival hemorrhage, eye pruritus, lacrimation increased, visual acuity reduced, blepharitis and punctate keratitis

Roclatan™ Phase 3 Month 12 Responder Analysis: Goal is to Achieve Lowest IOP Possible



At Month 12: % of Patients with IOP Reduced to 18 mmHg or Lower



*p<0.05, **p<0.01, ***p<0.0001

††Data on File
Based on Mercury 1 Interim Analysis 2

Roclatan™ has not been approved by any regulatory authority. For Investor Use

Roclatan™ Next Steps



- Roclatan™ NDA submission accepted, with March 14, 2019 PDUFA
- Current U.S. sales force will be trained on Roclatan™ in advance of PDUFA
- Commercial formulary access expected to be finalized post-approval
- Medicare Part D formulary submission to payers expected in April 2019



Expanding Aerie Franchise: Europe and Japan

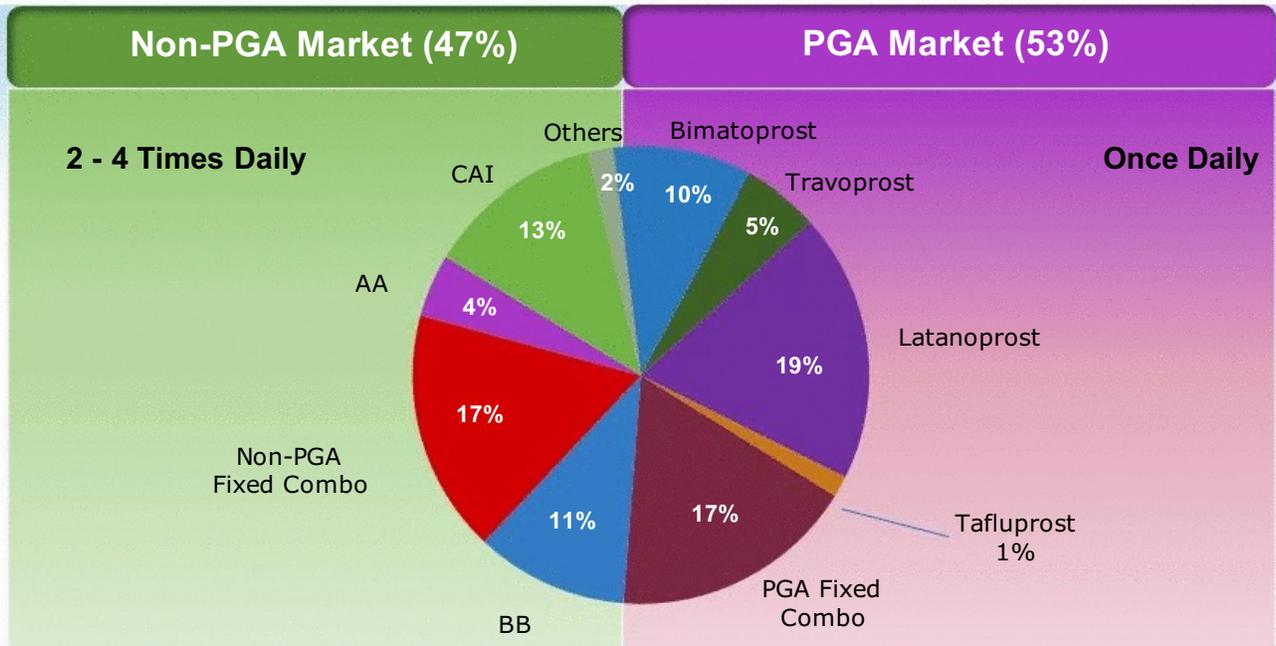
- **Europe** (2017 Europe “Big 5” Glaucoma Market: 91M units per year, 1.5X U.S. units)
 - Expect to file MAA for Rhopressa® in 2H 2018
 - Current clinical plan expected to satisfy European regulatory requirements (including Rocket 4 for Rhopressa® and Mercury 3 for Roclatan™)
 - Mercury 3: 6-month safety and 90-day efficacy registration trial comparing Roclatan™ for non-inferiority to a fixed-dose combo in Europe (Ganfort®)
 - Construction of Ireland Plant in process to support worldwide commercial supply
- **Japan** (2017 Glaucoma Market: 54M units per year)
 - Plan to advance clinical development on our own, establish office in Tokyo
 - Phase 1 completed and Phase 2 under way in the U.S. on Japanese and Japanese-Americans; additional Phase 2 to commence in Japan
 - Phase 3 trials expected to be conducted in Japan

Europe Glaucoma Market:

Aerie Expects to Commercialize on Its Own (if approved)



“Big 5” Europe Glaucoma Market – 2017
\$1.0B; 91M TRx*, Market Share in TRx



PGA: Prostaglandin Analogue; BB: Beta Blocker; AA: Alpha Agonist; CAI: Carbonic Anhydrase Inhibitor
 Sources: IQVIA Analytics Link at ex-manufacturer price level. *TRx calculated from IQVIA unit data (1 month = 1 TRx)

Advancing the Pipeline



- **Rhopressa®**
 - 24-hour IOP reduction
 - Potential in normal tension glaucoma
 - Aqueous humor dynamics (trabecular outflow, episcleral venous pressure)
 - Pseudoexfoliative glaucoma
 - Corneal healing

- **Retina Program Opportunities:**
 - **AR-1105** (dexamethasone steroid) potentially for DME
 - **AR-13503** (ROCK/PKC inhibitor) potentially for AMD and DME

- **Drug Delivery Platform**
 - Focused on ophthalmic sustained release technologies (DSM / PRINT®)

AR-13503 and AR-1105 are preclinical stage molecules and have not been approved by the FDA.
Additional potential Rhopressa® indications are being considered for further study and are not labeled indications.
Rhopressa® has not been approved by any regulatory authority other than the FDA.

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