AERIE PHARMACEUTICALS INC

FORM 8-K
(Current report filing)

Filed 07/19/17 for the Period Ending 07/19/17

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Industry	Biotechnology & Medical Research
Sector	Healthcare
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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): July 19, 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))

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 19, 2017, Aerie Pharmaceuticals, Inc. (the "Company") issued a press release announcing the topline 12-month safety results from the Company's Phase 3 "Mercury 1" registration trial for its product candidate, Roclatan ™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005%. A copy of the press release is furnished as Exhibit 99.1 hereto and is hereby incorporated by reference into this Item 7.01.

On or after July 19, 2017, representatives of the Company may present to various investors the information about the topline safety and efficacy results of Mercury 1 described in the slides attached to this report as Exhibit 99.2 hereto, which is hereby incorporated by reference into this Item 7.01.

The information in this Item 7.01 (including Exhibits 99.1 and 99.2) 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 exhibits relating to Item 7.01 shall be deemed to be furnished, and not filed:

99.1	Press Release dated July 19, 2017.
99.2	Roclatan ™ Mercury 1 Phase 3 12-month Topline Results.

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 19, 2017

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

EXHIBIT INDEX

Exhibit	Description
99.1	Press Release dated July 19, 2017.
99.2	Roclatan ™ Mercury 1 Phase 3 12-month Topline Results.

Exhibit 99.1

Aerie Pharmaceuticals Reports Positive Roclatan ™ (netarsudil/latanoprost ophthalmic solution) 0.02%/0.005% Phase 3 12-month Topline Safety Results

Roclatan ™ Successfully Demonstrates a Positive Safety Profile and Efficacy Levels Consistent with Previously Reported Results

Conference Call and Webcast Today, July 19, at 5:00 p.m. ET

IRVINE, Calif., July 19, 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 reported the successful 12-month safety results of the Company's "Mercury 1" Phase 3 registration trial for its fixed-dose combination product candidate, Roclatan ™ . Mercury 1 is a 12-month safety and efficacy trial which included a 90-day efficacy endpoint. As previously reported, both Mercury 1 and Mercury 2, the Company's second Phase 3 registration trial of Roclatan ™ , achieved their 90-day primary efficacy endpoints of demonstrating statistical superiority over each of its components at all measured time points, including Aerie product candidate Rhopressa ™ (netarsudil ophthalmic solution) 0.02%, and market-leading prostaglandin analogue (PGA) latanoprost, all of which were dosed once daily in the evening.

The purpose of the 12-month Mercury 1 study is to provide adequate safety data for an expected NDA (new drug application) submission to the FDA in the first half of 2018. While not primary endpoints, the study also included measurements of intraocular pressure (IOP) at 8 a.m., 10 a.m. and 4 p.m. at months six, nine and twelve. The 12-month safety and efficacy results of Mercury 1 were consistent with the 90-day results from the Mercury 1 and Mercury 2 trials, each of which evaluated patients with maximum baseline IOPs ranging from above 20 to below 36 mmHg (millimeters of mercury). Management will host a conference call with accompanying slides to discuss these results at 5:00 p.m. Eastern Time (ET) today. The accompanying slides will be available at Aerie's website, aeriepharma.com.

Roclatan ™ 12-Month Safety and Efficacy Highlights for Mercury 1

- Safety results for Roclatan ™ for the 12-month period were consistent with those observed for the 90-day efficacy period in the trial. There were no new adverse events that developed following the initial 90-day period, and there were no drug-related serious or systemic adverse events.

- As expected, the most common adverse event for Roclatan ™ was conjunctival hyperemia, or eye redness, which was observed in approximately 60 percent of patients, of which approximately 70 percent was determined to be mild by biomicroscopy. As observed in previous trials, hyperemia was sporadic, with only approximately 10 percent of patients with hyperemia across each physician visit during the 12-month period.

- The other Roclatan ™ adverse events observed during the 12-month trial are consistent with those observed during the initial 90-day efficacy period, including conjunctival hemorrhages (subconjunctival petechiae) and cornea verticillata.

- In addition to the primary efficacy endpoint at 90 days, IOPs were measured at 8 a.m., 10 a.m., and 4 p.m. at months six, nine and twelve. Roclatan ™ IOP lowering exceeded that of both latanoprost and Rhopressa ™ in a range from 1 to 3 mmHg. Levels of IOP lowering were consistent with those observed in the Mercury 1 and Mercury 2 90-day efficacy results for all arms of the study. Roclatan ™ also demonstrated consistent levels of IOP lowering across the 12-month study period.

- Roclatan ™ reduced mean diurnal IOPs to 16 mmHg or lower in 60 percent of patients, a significantly higher percentage than observed in the two comparator arms.

- The Rhopressa ™ arm of the study performed consistently with previous Phase 3 trials from both a safety and efficacy perspective. Rhopressa ™ also demonstrated consistent levels of IOP lowering across the 12-month study period. At baseline IOPs below 25 mmHg, Rhopressa ™ IOP lowering was similar to latanoprost at month 12.

“With these positive 12-month Mercury 1 data, we have again demonstrated the consistent and well-understood performance of Roclatan ™ and Rhopressa ™ from both a safety and efficacy perspective. Roclatan ™ has the potential to become the most efficacious IOP-lowering therapy to enter the market, if approved, bolstered by an overall favorable safety and tolerability profile. We continue to expect to submit our Roclatan ™ NDA (new drug application) in the first half of 2018,” said Vicente Anido, Jr., Ph.D., Chairman and Chief Executive Officer at Aerie.

Dr. Anido continued, “This data readout represents the last in our series of Phase 3 trials for both Roclatan ™ and Rhopressa ™ for approval in the U.S., and we are now actively engaged in preparations for the expected Rhopressa ™ commercialization next year.”

Richard A. Lewis, M.D., Aerie’s Chief Medical Officer, added, “As a clinician, I am very excited about the responder analysis data for Roclatan ™ showing such a profound drop in IOP. We now have a robust understanding of the Roclatan ™ safety profile and expect that clinicians will be highly satisfied with the 12-month safety and efficacy data.”

About Roclatan™

Roclatan™ is a once-daily eye drop that combines Rhopressa™, as described below, with latanoprost, a widely prescribed PGA. Based on the Company’s preclinical studies and clinical trials to date, Aerie believes that Roclatan™, if approved, would be the first glaucoma product to lower IOP through all known mechanisms: (i) increasing fluid outflow through the trabecular meshwork, the eye’s primary drain, (ii) increasing fluid outflow through the uveoscleral pathway, the eye’s secondary drain, (iii) reducing fluid production in the eye, and (iv) reducing episcleral venous pressure (EVP). By covering the full spectrum of known IOP-lowering mechanisms, Roclatan™ has the potential to provide a greater IOP-lowering effect than any currently approved glaucoma product.

The first Phase 3 registration trial for Roclatan ™ , named Mercury 1, is a 12-month safety and efficacy trial, which was just completed and is the subject of this press release. Mercury 1 had a successful 90-day efficacy readout in September 2016. The second Phase 3 registration trial, named Mercury 2, is a 90-day efficacy trial, which reported successful primary efficacy results in May 2017. The topline 90-day efficacy readouts for both Mercury 1 and Mercury 2 demonstrated that Roclatan ™ was statistically superior to each of its components, thus achieving their primary clinical endpoints. Aerie expects to submit a Roclatan ™ NDA to the U.S. Food and Drug Administration (FDA) in the first half of 2018. A third Phase 3 registration trial, named Mercury 3, is expected to commence in Europe in the third quarter of 2017. Mercury 3 is not necessary for approval in the U.S., but rather to facilitate regulatory approval and commercialization in Europe.

About Rhopressa™

Rhopressa ™ (netarsudil ophthalmic solution) 0.02%, is a novel eye drop that the Company believes, if approved, would become the only once-daily product available that, based on Aerie's preclinical and clinical studies to date, specifically targets the trabecular meshwork, the eye's primary fluid drain and the diseased tissue responsible for elevated 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 submission to the FDA in February 2017. There were two additional Phase 3 registration trials for Rhopressa ™ , named Rocket 3 and Rocket 4. Rocket 3 was a small 12-month safety-only study in Canada that was not necessary for the NDA submission and for which enrollment has been discontinued. Rocket 4, which was successfully completed in April 2017, was designed to provide adequate six-month safety data for regulatory filing purposes in Europe, and was also not necessary for the NDA submission. 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 Rhopressa ™ NDA submission as supportive. The FDA has set the Prescription Drug User Fee Act (PDUFA) goal date for the completion of the FDA's review of the Rhopressa ™ NDA for February 28, 2018.

Conference Call / Webcast Information

Aerie management will host a live conference call and webcast at 5:00 p.m. ET today to discuss the Roclatan ™ Phase 3 12-month safety and efficacy results from Mercury 1, including a review of the associated slides that are posted on Aerie's website, aeriepharma.com.

The live webcast and a replay may be accessed by visiting Aerie's website at http://investors.aeriepharma.com . Please connect to the Company's website at least 15 minutes prior to the live webcast to ensure adequate time for any software download that may be needed to access the webcast. Alternatively, please call (888) 734-0328 (U.S.) or (678) 894-3054 (international) to listen to the live conference call. The conference ID number for the live call is 48191718. Please dial in approximately 10 minutes prior to the call. Telephone replay will be available approximately two hours after the call. To access the replay, please call (855) 859-2056 (U.S.) or (404) 537-3406 (international). The conference ID number for the replay is 48191718. The telephone replay will be available until July 26, 2017.

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 for Rhopressa ™ (netarsudil ophthalmic solution) 0.02% was submitted to the FDA in February 2017, and, in May 2017, the FDA set the PDUFA 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.

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 topline Mercury 1 data presented herein is preliminary and based solely on information available to us as of the date of this press release and additional information about the results may be disclosed at any time. 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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Source: Aerie Pharmaceuticals, Inc.

Roclatan™
Mercury 1 Phase 3 12-month Topline Results

Important Information

Any discussion of the potential use or expected success of our product candidates is subject to our product candidates being approved by regulatory authorities.

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 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. 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.” In particular, the topline Mercury 1 data presented herein is preliminary and based solely on information available to us as of the date of this press release and additional information about the results may be disclosed at any time. 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.

Roclatan™ Achieves Positive 12-Month Safety and Efficacy Results

- Safety data over the 12 months were consistent with previous Roclatan™ 3-month results
- There were no drug-related serious or systemic adverse events
- The main adverse event for Roclatan™ was conjunctival hyperemia, which was reported in ~60% of patients, scored as mild for ~70% of these patients and sporadic
- IOP-lowering effect of Roclatan™ through Month 12 remained stable and consistent with the primary efficacy analysis at Month 3, maintaining superiority over both latanoprost and Rhopressa™
  - 1-3 mmHg greater than monotherapy with either latanoprost or Rhopressa™ throughout the duration of the study (i.e., Week 2, Week 6, Month 3, Month 6, Month 9 and Month 12)
  - At Month 12, Roclatan™ reduced mean diurnal IOPs to 16 mmHg or lower in 60% of patients, a significantly higher percentage than observed in the comparator arms

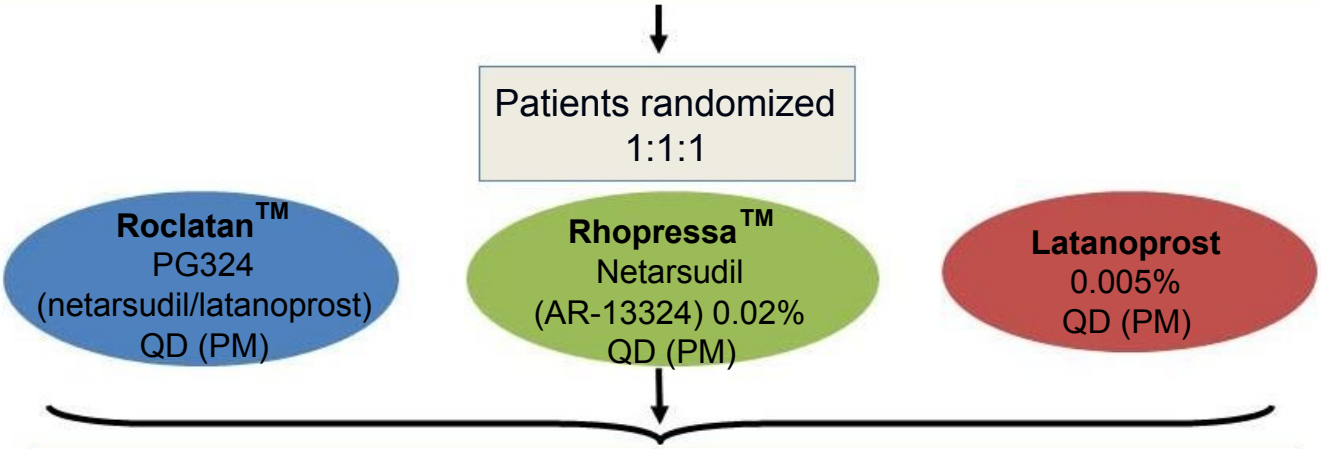
++Data on File
Based on Mercury 1 Topline 12-month

Mercury 1 Trial Design

Patients with open angle glaucoma (OAG) or ocular hypertension (OHT)

with IOP >20 mmHg and < 36 mmHg

N=718 subjects randomized at 58 US sites



Primary endpoints:

- Efficacy: Mean IOP at nine time points (08:00, 10:00, and 16:00 at Week 2, Week 6, and Month 3)
- Safety: Ocular and systemic safety during a 12-month treatment period

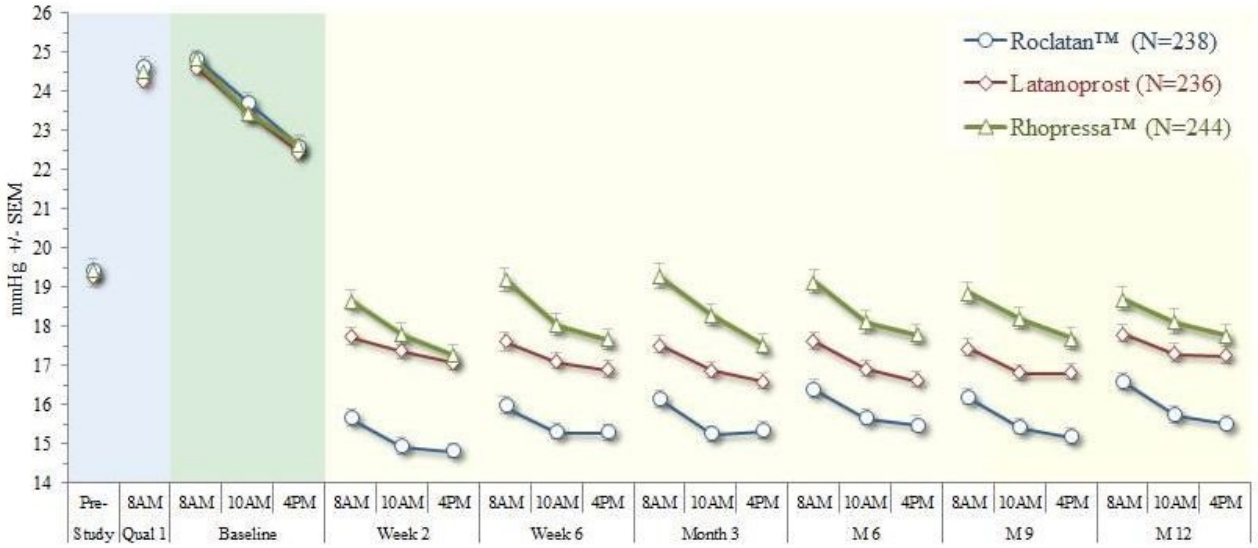
Disposition

	Roclatan™ N = 238	Rhopressa™ N = 244	Latanoprost N = 236
Completed Month 12	**159 (66.8%)**	**148 (60.7%)**	**203 (86.0%)**
Discontinued Prior to Month 12	**79 (33.2%)**	**96 (39.3%)**	**33 (14.0%)**
Reasons for Discontinuation			
Adverse Event	47 (19.7%)	53 (21.7%)	4 (1.7%)
Withdrawal of Consent	13 (5.5%)	9 (3.7%)	8 (3.4%)
Non-Compliant	0	1 (0.4%)	3 (1.3%)
Lost to Follow-up	5 (2.1%)	5 (2.0%)	4 (1.7%)
Lack of Efficacy	0	13 (5.3%)	1 (0.4%)
Disallowed Concurrent Medication	6 (2.5%)	7 (2.9%)	5 (2.1%)
Investigator Decision	2 (0.8%)	2 (0.8%)	0
Protocol Violation	6 (2.5%)	3 (1.2%)	8 (3.4%)
Other	0	3 (1.2%)	0

++Data on File
Based on Mercury 1 Topline 12-month

Roclatan™ Maintained Superior Efficacy Over Individual Components for 12 Months

Mean IOP at Each Time Point (ITT)

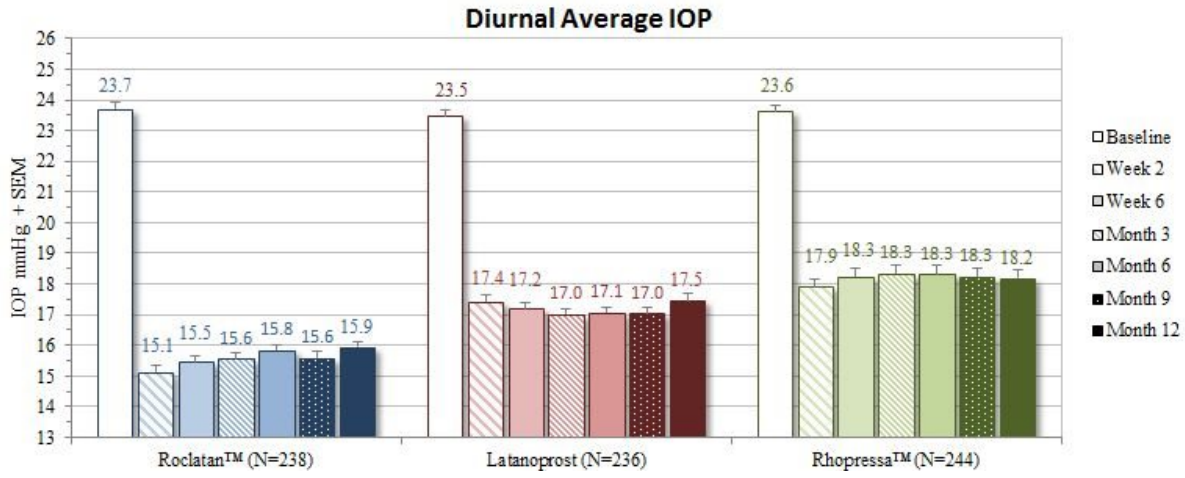


- Roclatan™ statistically superior to latanoprost and Rhopressa™ at all time points
- Roclatan™ IOP-lowering 1-3 mmHg greater than monotherapy through Month 12

++Data on File
Based on Mercury 1 Topline 12-month

Roclatan™ Maintained Superior Efficacy Over Individual Components for 12 Months

Mean Diurnal IOP at Each Visit (ITT)

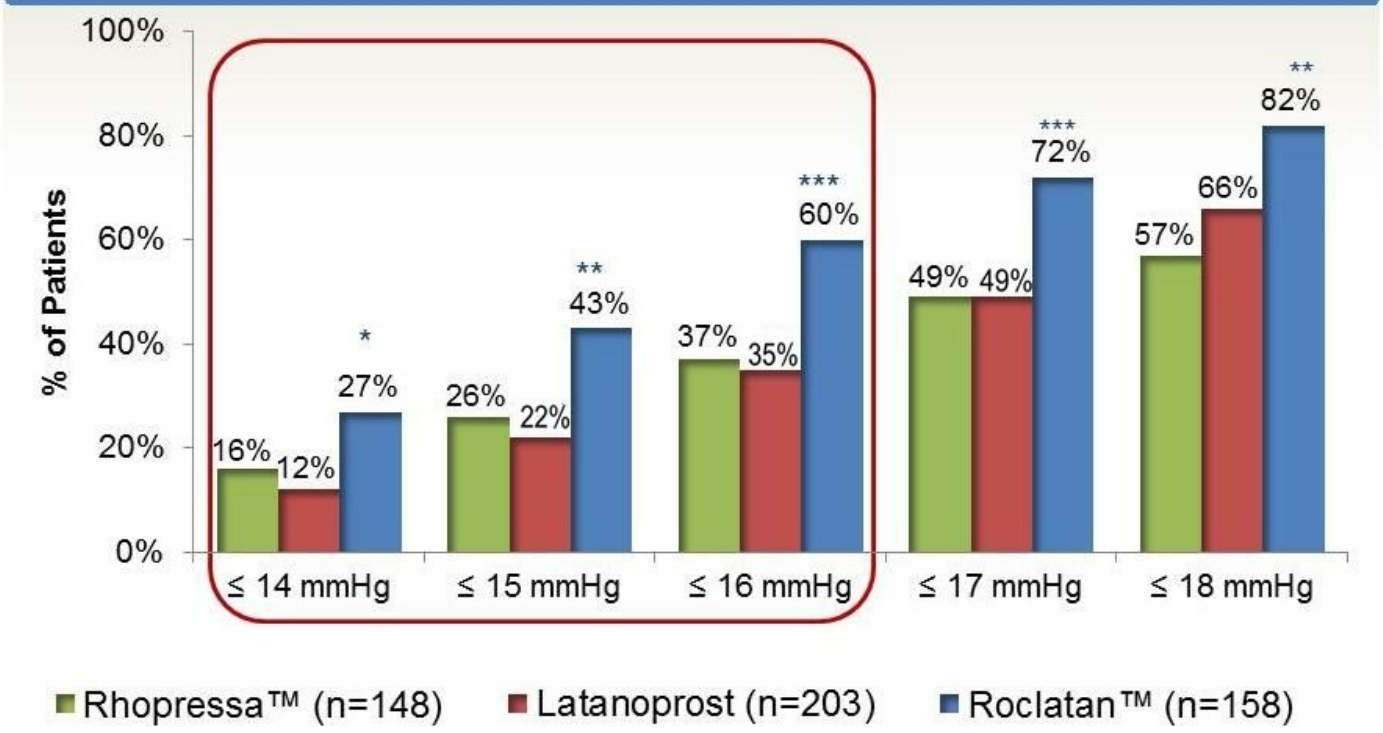


p<0.0001 at All Visits vs. Latanoprost and Rhopressa™

++Data on File
Based on Mercury 1 Topline 12-month

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

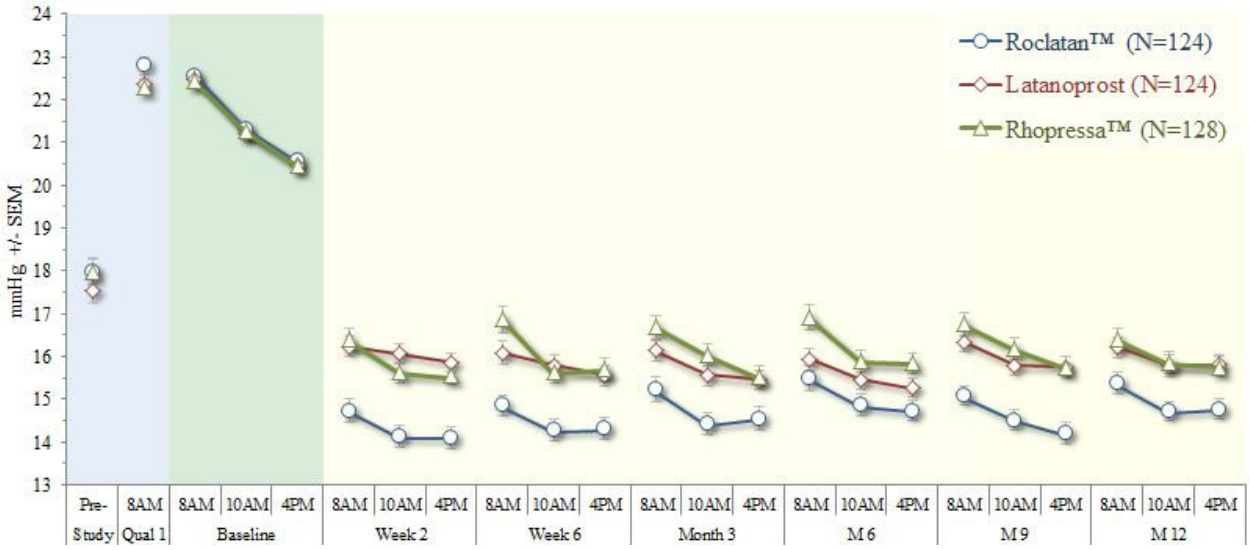


*p<0.05, **p<0.01, ***p<0.0001

++Data on File
Based on Mercury 1 Topline 12-month

Efficacy in Subjects with Baseline IOP <25 mmHg

Mean IOP at Each Time Point (ITT)

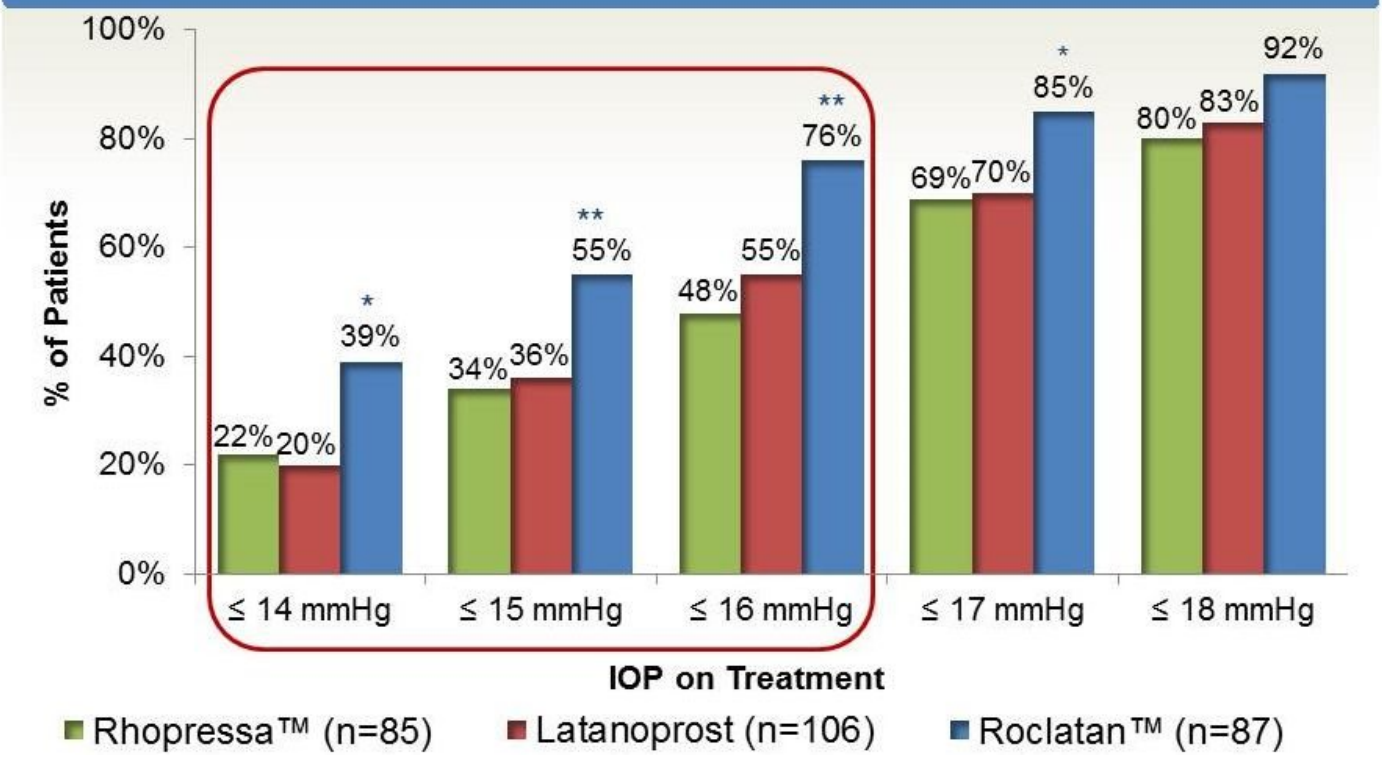


- Rhopressa™ efficacy similar to latanoprost and stable for 12 months

++Data on File
Based on Mercury 1 Topline 12-month

Roclatan™ Responder Analysis
Baseline IOP < 25 mmHg

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

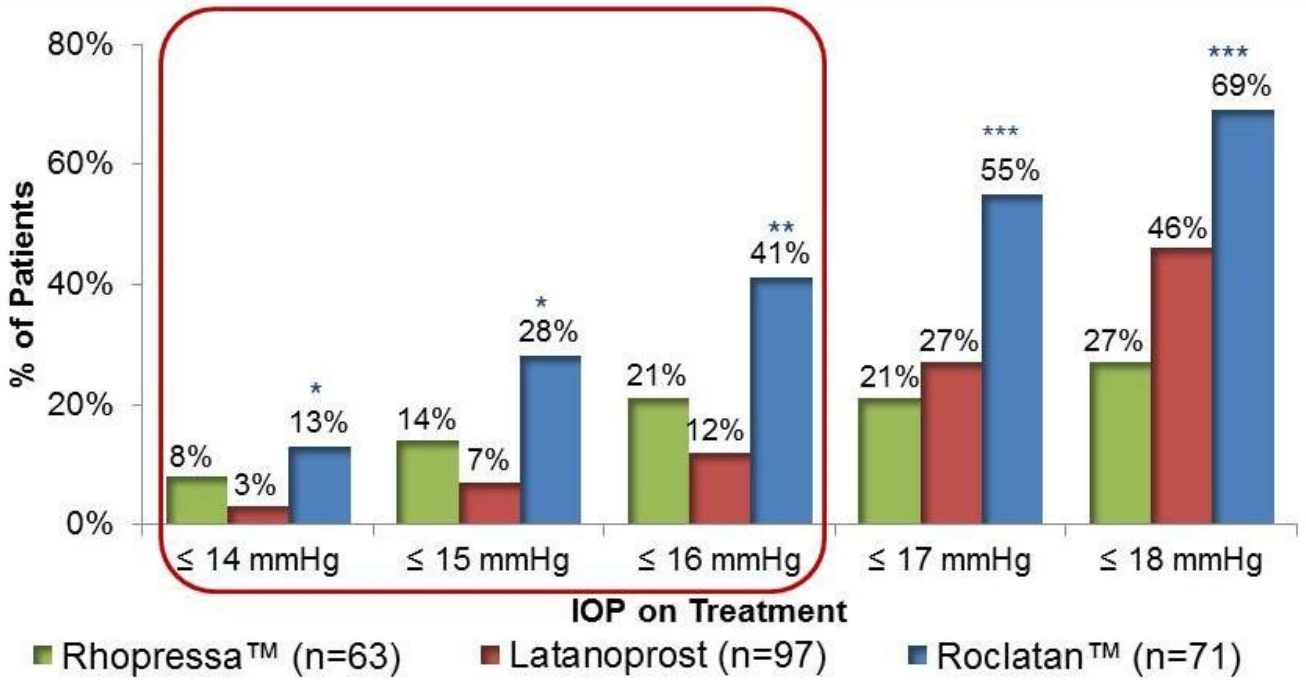


*p<0.05, **p<0.01

++Data on File
Based on Mercury 1 Topline 12-month

Roclatan™ Responder Analysis
Baseline IOP≥25 mmHg

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



*p<0.05 vs Latanoprost
**p<0.05 vs Rhopressa™, p<0.0001 Latanoprost
***p<0.0001 vs Rhopressa™, p<0.01 Latanoprost

++Data on File
Based on Mercury 1 Topline 12-month

Safety/Tolerability Overview of Roclatan™

- There were no drug-related serious adverse events (SAEs) and no evidence of treatment-related systemic effects
- The most common adverse event was conjunctival hyperemia with ~60% incidence, scored as mild on biomicroscopy for ~70% of these patients and sporadic
- Other ocular AEs
  - AEs occurring in ~5-18% of subjects receiving Roclatan™ included: cornea verticillata, conjunctival hemorrhage, eye pruritus, lacrimation increased, visual acuity reduced, blepharitis and punctate keratitis.

++Data on File
Based on Mercury 1 Topline 12-month

Roclatan™ Phase 3 Safety Profile

Adverse Events (≥5.0% in any group)	Roclatan™ n=238	Rhopressa™ n=243	Latanoprost n=237
Eye Disorders			
Conjunctival Hyperemia	150 (63.0%)	125 (51.4%)	52 (21.9%)
Conjunctival Hemorrhage	31 (13.0%)	44 (18.1%)	3 (1.3%)
Cornea Verticillata	42 (17.6%)	33 (13.6%)	0
Eye Pruritus	27 (11.3%)	22 (9.1%)	3 (1.3%)
Punctate Keratitis	12 (5.0%)	18 (7.4%)	10 (4.2%)
Lacrimation Increased	17 (7.1%)	20 (8.2%)	1 (0.4%)
Visual Acuity Reduced	13 (5.5%)	13 (5.3%)	6 (2.5%)
Vision Blurred	11 (4.6%)	15 (6.2%)	3 (1.3%)
Blepharitis	14 (5.9%)	8 (3.3%)	5 (2.1%)
Administration Site Conditions			
Instillation site pain	55 (23.1%)	60 (24.7%)	18 (7.6%)

Patients with known contraindications or hypersensitivity to latanoprost were excluded

++Data on File
Based on Mercury 1 Topline 12-month

Roclatan™ Conjunctival Hyperemia Was Sporadic And Severity Did Not Increase With Continued Dosing

- Hyperemia severity did not increase with continued dosing
- Hyperemia was sporadic
  - Only ~10% of patients had hyperemia on each study visit day from week 2 to month 12 (~7% Rhopressa™, ~3% latanoprost)
- Only ~8% of all patients discontinued due to hyperemia (~7% of all patients at Month 3)

++Data on File
Based on Mercury 1 Topline 12-month

Roclatan™ Once-Daily Performance Summary

- Consistent statistically superior efficacy over both latanoprost and Rhopressa™ at all time points demonstrated in 2 Phase 3 trials (Mercury 1 and Mercury 2)
- IOP-lowering effect was greater (1-3 mmHg) than monotherapy with either latanoprost or Rhopressa™ throughout the duration of the study
- Stable efficacy through 12 months
- Well tolerated with no evidence of treatment-related serious or systemic effects

++Data on File
Based on Mercury 1 and Mercury 2

Rhopressa™ Once-Daily Performance Summary

Rhopressa™ efficacy similar to latanoprost with baseline IOP < 25 mmHg

Rhopressa™ maintained consistent IOP lowering across all baseline IOPs including ≥ 25 mmHg

Stable efficacy through 12 months

Adverse event profile consistent with previous studies

++Data on File
Based on Mercury 1 Topline 12-month

Key Upcoming Milestones

Rhopressa™

- PDUFA February 28, 2018
  - - Expected FDA Advisory Committee
- Initiating clinical program for Japan market (Phase 1 and 2 to be conducted in the U.S. in Japanese patients)
  - - To commence in Q3/Q4 2017

Roclatan™

- NDA filing expected 1H 2018
- Mercury 3 (Europe): 6-month study, comparing to Ganfort®
  - - To commence in Q3 2017