Aerie Pharmaceuticals, Inc.
(Exact name of registrant as specified in its charter)

Delaware 001-36152 20-3109565
(State or other jurisdiction  (Commission  (I.R.S. Employer
of incorporation) File Number) Identification Number)

135 US Highway 206, Suite 15 07921
Bedminster, New Jersey  (Address of principal executive offices) (Zip code)

Registrant’s telephone number, including area code: (908) 470-4320

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 January 9, 2014, Aerie Pharmaceuticals, Inc. (the “Company”) issued a press release announcing the results from the Company’s recently completed Phase 1 pharmacokinetics study. 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 January 9, 2014, representatives of the Company may present to various investors the information about the Company as described in the slides attached to this report as Exhibit 99.2 hereto. Exhibit 99.2 is hereby incorporated by reference into this Item 7.01.

The information in this Item 7.01 (including Exhibits 99.1 and 99.2) are 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:


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: January 9, 2014

By: /s/ Richard J. Rubino

Richard J. Rubino
Chief Financial Officer
<table>
<thead>
<tr>
<th>Exhibit</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>99.2</td>
<td>Company Overview presentation dated January 9, 2014</td>
</tr>
</tbody>
</table>
Aerie Pharmaceuticals Reports Positive Results for Lead Candidate AR-13324 in Normotensive Individuals

Results Also Suggest a Potential New Mechanism of Action

Aerie Reaffirms Timeline to Commence Two Phase 3 Studies by mid-2014

BEDMINSTER, N.J. & RESEARCH TRIANGLE PARK, N.C. & NEWPORT BEACH, CALIF. — (BUSINESS WIRE) — Aerie Pharmaceuticals, Inc. (NASDAQ:AERI), a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of first-in-class glaucoma therapies, today announced top-line results from the Company’s recently completed Phase 1 pharmacokinetics (PK) study, in which AR-13324 eye drops were administered once-daily to 18 healthy individuals over an eight-day period to assess systemic exposure to the drug. In addition to the primary PK outcome of the study, the drug’s effect on intraocular pressure (IOP) was also measured. The completion of the PK study is an important step in preparing for two planned Phase 3 registration studies of AR-13324, which are expected to commence by mid-2014.

The PK results demonstrated very low systemic exposure to the drug, with blood levels at or below the limit of detection of 0.1 ng/mL at all time points. In addition, there were no drug-related effects on systemic safety parameters such as blood pressure and heart rate. All study subjects had IOPs in the normotensive range of 12 to 21 mmHg, with an average diurnal IOP for the group of approximately 16 mmHg prior to dosing. After eight days of dosing, once-daily administration of AR-13324 reduced the average diurnal IOP to approximately 11 mmHg, representing a decrease of approximately 5 mmHg, or over 30 percent.

Brian Levy, O.D., M.Sc., Aerie’s Chief Medical Officer, commented, “The large reduction in IOP achieved by AR-13324 in normotensive individuals distinguishes AR-13324 from currently available glaucoma drugs, which are typically less effective in subjects with low baseline IOPs. Preclinical normotensive animal studies have shown similar results. These data are consistent with the results of our previous Phase 2b clinical trial in which AR-13324 demonstrated consistent IOP lowering irrespective of baseline IOP, whereas the comparator latanoprost demonstrated reduced efficacy at lower baseline IOPs, as disclosed in our recently filed registration statement.”

“As documented in the Baltimore Eye Survey, patients with low-to-moderately elevated IOPs at the time of diagnosis represent the significant majority of glaucoma patients,” stated David Epstein, M.D., Chairman, Department of Ophthalmology, Duke University School of Medicine, and Chairman of Aerie’s Scientific Advisory Board. “Very commonly, glaucoma patients require a low normal IOP to prevent further progression, and a drug that could achieve this would be a great advance. I am encouraged by the recent

1 Hedman and Alm; European Journal Ophthalmology; 2000.
data and previous clinical findings for AR-13324, and believe that its significant IOP-lowering effect at lower baseline IOPs could reflect an additional mechanism of action beyond the dual mechanisms of which we are already aware, one that could involve the reduction of episcleral venous pressure.”

As background, IOP is determined by the contributions of four distinct MOAs: aqueous humor (eye fluid) production, resistance to aqueous outflow via the trabecular meshwork and uveoscleral pathway, and episcleral venous pressure. Historical studies have shown that episcleral venous pressure accounts for approximately half of IOP in normotensive subjects and approximately one-third of IOP in patients with pressures of 24 to 30 mmHg. When episcleral venous pressure is lowered, aqueous humor is able to flow more freely from the eye. Aerie plans to conduct additional studies to directly measure the effect of AR-13324 on episcleral venous pressure and better understand this potential new mechanism of action.

**AR-13324 Clinical Program**

Aerie’s successful 28-day Phase 2b trial demonstrated that once-daily administration of AR-13324 produced significant IOP lowering in the range of 5.7 to 6.2 mmHg in patients with elevated IOP, with a differentiated efficacy profile of consistent IOP lowering across all baseline IOPs tested in the clinical trial. The multiple mechanisms of action for AR-13324 include increasing fluid outflow through the trabecular pathway or primary drain, reducing fluid production, and potentially also lowering episcleral venous pressure. Aerie plans to commence two Phase 3 registration trials of AR-13324 in mid-2014, with total expected enrollment of approximately 1,200 patients. Based on the Phase 2b clinical trial results, previous discussions with the FDA, and the recent findings on the potential new mechanism of action, the Company plans to recruit patients into the Phase 3 clinical trials with baseline IOPs ranging from 21 to 26 mmHg. The trials will measure efficacy over three months and safety over 12 months. The primary efficacy endpoint of the trials will be to demonstrate non-inferiority of IOP lowering for AR-13324 (dosed once daily) compared to timolol (dosed twice daily).

Assuming the registration trials commence on schedule, three-month efficacy results are expected to be released in mid-2015, and should the trials be successful, Aerie expects to submit an NDA filing for AR-13324 by mid-2016.

**PG324 Clinical Program**

PG324 is a once-daily eye drop that combines AR-13324 with latanoprost, a prostaglandin analogue that is the most widely prescribed glaucoma drug. If approved, Aerie believes that PG324 would be the first glaucoma product to lower IOP through potentially four mechanisms of action: increasing fluid outflow through the trabecular pathway or primary drain, increasing fluid outflow through the uveoscleral pathway or secondary drain, reducing fluid production in the eye, and potentially also lowering episcleral venous pressure. The Company believes that PG324, if approved, would be the only glaucoma product that covers the full spectrum of IOP-lowering mechanisms, thereby providing a greater IOP-lowering effect than any currently approved glaucoma product.
Aerie is preparing to bring PG324 into a 28-day Phase 2b clinical trial that is expected to include approximately 300 patients and will compare two concentrations of PG324 to latanoprost and to AR-13324, all dosed once daily. The efficacy endpoint will be superiority of PG324 to each of its components. Results of the PG324 Phase 2b trial are currently expected in mid-2014.

About Aerie Pharmaceuticals, Inc.

Aerie is a clinical-stage pharmaceutical company focused on the discovery, development and commercialization of first-in-class glaucoma therapies. The Company is preparing for two Phase 3 registration trials, where the primary efficacy endpoint will be to demonstrate non-inferiority of IOP lowering for AR-13324 (dosed once daily) compared to timolol (dosed twice daily). The Company also is preparing for a Phase 2b clinical trial of its fixed-dose combination product PG324, where the primary efficacy endpoint will be to demonstrate superiority of PG324 to each of its components.

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,” “continue,” “estimates,” “anticipates,” “expects,” “plans,” “intends,” “may,” “could,” “might,” “will,” “should” 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 clinical trials and anticipated Phase 3 and Phase 2b clinical trials for our current product candidates, including statements regarding the timing of initiation and completion of the 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 estimates regarding anticipated capital requirements and our needs for additional financing; our expectations regarding the clinical effectiveness of our product candidates and results of our clinical trials; the potential advantages of our product candidates; our ability to protect our proprietary technology and enforce our intellectual property rights; and our expectations related to the use of proceeds from our initial public offering. 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” section contained in our final prospectus from our initial public offering which is on file with the Securities and Exchange Commission (SEC), and in the quarterly and annual reports that we file with the 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.
Company Overview
January 9, 2014
Any discussion of the potential use or expected success of our product candidates is subject to our product candidates being approved by regulatory authorities. In addition, any discussion of clinical data results for our AR-13324 product candidate relate to the results in our Phase 2 clinical trials. Our product candidate PG324 has only been tested in preclinical animal models.

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, including beliefs, expectations, estimates, projections and statements relating to our business plans, prospects and objectives, and the assumptions upon which those statements are based. Words such as “may,” “will,” “should,” “would,” “could,” “believe,” “expects,” “anticipates,” “plans,” “intends,” “estimates,” “targets,” “projects” 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 our prospectus filed with the SEC on October 28, 2013, particularly in the sections titled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operation.” 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 – Next Generation in Glaucoma Therapies

- **Large Market Opportunity - $4.5B US/EU/JP Market**
  - Significant unmet needs - 50% of patients require more than one drug
  - No PGA fixed-combination products approved in the US

- **Proprietary, Differentiated First-in-Class Glaucoma Pipeline**
  - Both ROCK & NET inhibition - First new MOAs in two decades
  - Potential additional new MOA – lowering of EVP

- **AR-13324: Novel Dual-Action, Once-Daily Therapy**
  - Phase 3 expected to begin mid-2014; efficacy data expected mid-2015
  - NDA filing expected by mid-2016

- **PG324: Breakthrough Triple-Action, Once-Daily Therapy**
  - Fixed combination of AR-13324 and PGA latanoprost
  - Phase 2b data expected mid-2014; Phase 3 readiness expected mid-2015

- **All Products Developed Internally - Own Class & Compounds**
  - Patent protection through at least 2030 in the US
  - All rights retained with no partnerships
### Aerie Strategy Overview

**Advance First-in-Class Glaucoma Treatments**
- AR-13324 Phase 3 efficacy results expected mid-2015; NDA filing expected mid-2016
- PG324 Phase 2b results expected mid-2014; Initiate prep for Phase 3 trials mid 2014-2015

**Establish Commercial Capabilities**
- Build own US commercial infrastructure with ~100 sales representatives
- Target ~10,000 high-prescribing eye care professionals

**Maximize Portfolio Value Ex-US**
- Explore partnership opportunities outside US through collaborations & licensing
- Global reach to Europe, Japan and emerging markets

**Expand Commercial Offerings**
- Explore additional ophthalmic product candidates
# Aerie’s Experienced Leadership Team

## Executive Team

<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vince Anido, Jr., PhD</td>
<td>Chairman &amp; CEO</td>
</tr>
<tr>
<td>Thomas Mitro</td>
<td>President &amp; COO</td>
</tr>
<tr>
<td>Brian Levy, OD, MSc</td>
<td>CMO</td>
</tr>
<tr>
<td>Casey Kopczynski, PhD</td>
<td>CSO</td>
</tr>
<tr>
<td>Richard Rubino</td>
<td>CFO</td>
</tr>
</tbody>
</table>

## Board Experience

- ISTA Pharmaceuticals
- Allergan
- Omeros
- Bausch + Lomb
- Nexis Vision
- Exelixis
- Ercole Biotech
- Medco
- IBM
- PwC
- Regeneron
- Alcon
- TPG Biotech
- Alta Partners
- Clarus Ventures
- Sofinnova Ventures
- Osage Venture Capital
- TPG Biotech
- Clarus Ventures
- Sofinnova Ventures
- Osage Venture Capital
Discovered new *Rho Kinase Inhibitors* and the novel *Dual-Action ROCK/NET Inhibitor* drug class
- >1,500 ROCK and ROCK/NET inhibitors screened and characterized

Pursued parallel clinical development of two franchises to allow data driven selection of best product candidates

Dual-Action AR-13324 franchise selected for future development
- Superior efficacy profile in clinic
- Longer duration of action
- 10-160x more potent than previous clinical stage ROCK inhibitors
- Superior safety profile in long-term ocular toxicology study
- Consistent IOP lowering regardless of baseline IOP

Aerie is a Leader in Rho Kinase R&D

ROCK/NET: Rho Kinase / Norepinephrine Transporter
Aerie's Pipeline is Advancing Rapidly

<table>
<thead>
<tr>
<th>Product</th>
<th>Preclinical</th>
<th>IND</th>
<th>Phase 1/2a</th>
<th>Phase 2b</th>
<th>Phase 3</th>
<th>NDA</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR-13324 ROCK/NET Inhibitor</td>
<td></td>
<td></td>
<td>Dual-Action</td>
<td>2014</td>
<td></td>
<td>2016</td>
</tr>
<tr>
<td>PG324 Combination AR-13324 + Latanoprost</td>
<td></td>
<td></td>
<td>Triple-Action</td>
<td>P2b 2014</td>
<td></td>
<td></td>
</tr>
<tr>
<td>AR-13533 ROCK/NET 2nd Generation</td>
<td></td>
<td></td>
<td>Dual-Action</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Clinical Trials for Glaucoma Recruit Quickly and Have Clear Endpoints
Glaucoma Market
Significant Glaucoma Market Opportunities

- Largest Rx market in ophthalmology
  - US 28.5M Rx; annual US sales $1.9B ($4.5B US/EU/JP)
- 2.2M glaucoma patients in the US and growing due to aging of population
  - Glaucoma is a leading cause of blindness in US and WW
- ~50% of patients use multiple medications to control disease – compliance and tolerability are issues
- No drugs launched with new MOA in the past 20 years
Currently Prescribed Glaucoma Therapies

US Glaucoma Market
IMS TRx data, FY 2012

- Latanoprost, 27%
- Travoprost, 12%
- Bimatoprost, 11%
- CAI, 6%
- AA, 14%
- BB, 15%
- BB Fixed Combo, 14%

Half of TRx are Written for Non-PGA Products

PGA: Prostaglandin Analogue; BB: Beta Blocker; AA: Alpha Agonist; CAI: Carbonic Anhydrase Inhibitor
Novel Products Address All IOP Control Mechanisms, and May Lower EVP

- AA, BB, CAI: Inflow (fluid production)
- PGAs: Outflow Secondary Drain (Uveoscleral)
- Triple Action PG324
- Dual Action AR-13324

Outflow
Primary Drain (Trabecular Meshwork)
## The Competitive Landscape

<table>
<thead>
<tr>
<th></th>
<th>Clinical Efficacy</th>
<th>Dosing/Day</th>
<th>Tolerability</th>
<th>Peak Product Sales* (US/EU)</th>
<th>Targeting Diseased Tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>PGA</td>
<td>High</td>
<td>1x</td>
<td>Hyperemia Iris Color</td>
<td>$1.7B</td>
<td>No</td>
</tr>
<tr>
<td>Beta Blocker</td>
<td>Moderate</td>
<td>2x</td>
<td>Cardiopulmonary Contraindications</td>
<td>&gt;$500M</td>
<td>No</td>
</tr>
<tr>
<td>CAI</td>
<td>Low</td>
<td>2 - 3x</td>
<td>Sulfonamide Contraindication Bitter Taste</td>
<td>&gt;$500M</td>
<td>No</td>
</tr>
<tr>
<td>Alpha Agonist</td>
<td>Low</td>
<td>2 - 3x</td>
<td>Allergy Drowsiness</td>
<td>&gt;$400M</td>
<td>No</td>
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<tr>
<td>AR-13324</td>
<td>High; Moderate</td>
<td>1x</td>
<td>Hyperemia</td>
<td></td>
<td>Yes</td>
</tr>
<tr>
<td>PG324</td>
<td>Potentially Highest</td>
<td>1x</td>
<td>TBD</td>
<td></td>
<td>Yes</td>
</tr>
</tbody>
</table>

* Peak sales for best-in-class franchise
### Glaucoma Competitors in Pipeline

**New MOAs**

<table>
<thead>
<tr>
<th>Drug</th>
<th>MOA</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>AR-13324 (Aerie)</td>
<td>ROCK/NET inhibitor (qd)</td>
<td>Phase 2b</td>
</tr>
<tr>
<td>K-115 (Kowa)</td>
<td>ROCK inhibitor (bid)</td>
<td>Phase 3 (Japan)</td>
</tr>
<tr>
<td>AMA0076 (Amakem)</td>
<td>ROCK inhibitor (bid)</td>
<td>Phase 2a</td>
</tr>
<tr>
<td>INO-8875 (Inotek)</td>
<td>Adenosine-A1 agonist (bid)</td>
<td>Phase 2</td>
</tr>
<tr>
<td>LX7101 (Lexicon)</td>
<td>LIMK2 inhibitor (bid)</td>
<td>Phase 1/2</td>
</tr>
<tr>
<td>SYL040012 (Sylentis)</td>
<td>RNAi beta blocker (bid)</td>
<td>Phase 2</td>
</tr>
</tbody>
</table>

**New PGAs - not usable as add-on to current PGAs**

<table>
<thead>
<tr>
<th>Drug</th>
<th>MOA</th>
<th>Phase</th>
</tr>
</thead>
<tbody>
<tr>
<td>BOL-303259 (B+L)</td>
<td>NO donating latanoprost (qd)</td>
<td>Phase 3</td>
</tr>
<tr>
<td>DE-117 (Santen)</td>
<td>EP2 agonist (qd)</td>
<td>Phase 2a</td>
</tr>
<tr>
<td>ONO-9054 (Ono)</td>
<td>FP/EP3 agonist (qd)</td>
<td>Phase 1</td>
</tr>
</tbody>
</table>

AR-13324 is the only new MOA drug dosed once-daily
### Aerie Franchise: Highly Differentiated Product Profiles

<table>
<thead>
<tr>
<th>AR-13324 Dual-Action</th>
<th>PG324 Triple-Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Single drop, once-daily</td>
<td>Single drop, once-daily</td>
</tr>
<tr>
<td>1 drug - 2 MOAs, and may also lower EVP</td>
<td>Combination of 2 drugs -3 MOAs, and may also lower EVP</td>
</tr>
<tr>
<td>Well tolerated; no systemic drug-related AEs</td>
<td>Well tolerated; no systemic drug-related AEs</td>
</tr>
<tr>
<td>Efficacy expected to be ≥ current non-PGA drugs</td>
<td>Efficacy expected to be superior to PGA monotherapy</td>
</tr>
</tbody>
</table>

**Future non-PGA drug of choice**

**Future drug of choice for all glaucoma patients**

PGA: Prostaglandin Analogue
New Dual-Action Drug Class:
AR-13324
• Open-angle glaucoma is a progressive, irreversible and chronic disease of the eye
  - Typical patient age >60 years

• Elevated intraocular pressure (IOP) can lead to loss of vision and eventual blindness

• Lowering IOP slows or halts progression
  - 5 mmHg IOP reduction reduces risk of disease progression by 50%*

• Cause of elevated IOP is degeneration of primary fluid drain (trabecular meshwork)

*Early Manifest Glaucoma Trial (Heijl, 2002; Leske, 2003); Ocular Hypertension Treatment Study (Kass, 2002)
1. ROCK inhibition relaxes TM
2. NET inhibition reduces fluid production
3. ROCK inhibition may lower Episcleral Venous Pressure (EVP)
### ~80% of Glaucoma IOPs Are ≤ 26 mmHg at Time of Diagnosis

**Baltimore Eye Survey**

<table>
<thead>
<tr>
<th>Baseline IOP (mmHg)</th>
<th>Percentage of POAG Patients Identified</th>
<th>Cumulative Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>≤ 15</td>
<td>13%</td>
<td>13%</td>
</tr>
<tr>
<td>16-18</td>
<td>24%</td>
<td>37%</td>
</tr>
<tr>
<td>19-21</td>
<td>22%</td>
<td>59%</td>
</tr>
<tr>
<td>22-24</td>
<td>19%</td>
<td>78%</td>
</tr>
<tr>
<td>25-29</td>
<td>10%</td>
<td>88%</td>
</tr>
<tr>
<td>30-34</td>
<td>9%</td>
<td>97%</td>
</tr>
<tr>
<td>≥ 35</td>
<td>3%</td>
<td>100%</td>
</tr>
</tbody>
</table>

10,444 individuals were screened for the prevalence of Primary Open-Angle Glaucoma (POAG)

AR-13324 Phase I PK Results Support Potential New MOA

- In healthy volunteers with normotensive IOP of 12 – 21 mmHg, AR-13324 lowered IOP by over 30% on D8
- Currently available glaucoma drugs are typically less effective at lower IOPs
- High efficacy at these baselines suggest a lowering of EVP – a potential new MOA
- EVP contributes up to half of IOP
- In Baltimore Eye Survey, ~60% of glaucoma patients at the time of diagnosis had low IOPs (< 21 mmHg)
- PK analysis showed low systemic exposure and no drug-related effects on systemic safety parameters
AR-13324 Demonstrated Strong IOP Lowering in Phase 2b

- Once-daily PM dosing of 0.02% AR-13324 is highly effective
  - IOP -5.7 and -6.2 mmHg on D28 and D14
  - Consistent efficacy through D28
- AR-13324 efficacy results ≥ current non-PGA drugs
- Favorable tolerability profile
- No systemic side effects

13 glaucoma NCEs advanced from Phase 2 to Phase 3 since 1970s - All approved
The only AR-13324 finding of note was hyperemia
- Scored as trace, mild or moderate, and transient for majority of patients
- No drug-related systemic adverse events

On last day of study (Day 28 at 8 AM), mild and moderate conjunctival hyperemia was observed in 24% of AR-13324 0.02% patients and 11% of latanoprost patients
- Frequency of hyperemia decreased throughout the study for AR-13324 and increased for latanoprost

A 12-week study by Parrish et. al. (2003) compared the three most highly prescribed PGAs for frequency of hyperemia
- Latanoprost: 16% frequency
- Travoprost: 27% frequency
- Bimatoprost: 35% frequency
AR-13324 and latanoprost clinically and statistically equivalent in patients with moderately elevated IOPs of 22 - 26 mmHg

Latanoprost loses ~1 mmHg efficacy in patients with IOPs of 22 - 26 mmHg vs. 22 - 36 mmHg

AR-13324 maintains consistent efficacy in patients with moderately elevated IOPs

Phase 2b baseline IOP entry requirements: 24, 22, 22 mmHg (8am, 10am, 4pm)
Latanoprost and Timolol Show Reduced Efficacy at Lower Baseline IOPs

- Latanoprost and timolol lose 0.5 mmHg efficacy for every 1 mmHg drop in baseline IOP
- Timolol less effective than latanoprost at all baselines
- AR-13324 equivalent/non-inferior to latanoprost at baselines 22 – 26 mmHg
- Timolol is the standard comparator for glaucoma Phase 3 trials

Pooled data from three latanoprost registration studies. Hedman and Alm; European Journal Ophthalmology; 2000
AR-13324 Registration Trial Design

- Primary efficacy endpoint: IOP at all time points through Day 90

- Non-inferiority design vs. timolol
  - 95% CI within 1.5 mmHg at all time points, within 1.0 mmHg at a majority of time points

- Planned entry IOP: Minimum 21 mmHg, maximum 26 mmHg
  - FDA has agreed to Aerie proposal for entry IOPs with no impact on label
  - AR-13324 non-inferior to latanoprost at entry IOPs of 22-26 mmHg in Phase 2b

- Start mid-2014; 90 day safety and efficacy data expected mid-2015; NDA filing expected mid-2016
Triple-Action Fixed Combination:
PG324
AR-13324 FIXED COMBINATION WITH LATANOPROST

1. ROCK inhibition restores TM outflow
2. NET inhibition reduces fluid production
3. ROCK inhibition may lower Episcleral Venous Pressure
4. PGA receptor activation increases uveoscleral outflow
PG324: Triple-Action Fixed Combination

- First product to lower IOP through all three known mechanisms, and also potentially lower EVP
  - Once-daily: 1 drop, 2 drugs, 3 MOAs
- High efficacy in predictive primate model
- Human proof of concept established in prior ROCKi/PGA combination trials
  - Demonstrated significant IOP lowering beyond PGA alone
- Potential for maximal medical therapy in a single eye drop
AR-13324 formulated with market-leading latanoprost
  - Latanoprost has largest prescription base in glaucoma
  - Facilitates use as first-line therapy
  - Eases switch from latanoprost monotherapy

Combinations constitute an important growth segment of glaucoma market internationally
  - US lags - no PGA fixed-combination glaucoma drugs in the US
  - Powerful compliance rationale for life-long medication users
  - Beneficial to payors and patients

Expected to be first PGA fixed-combination product in the US
PG324 Phase 2b Clinical Trial Design

Phase 2b Protocol
PG324 0.01% vs. PG324 0.02% vs. AR-13324 0.02% vs. Latanoprost
All dosed QD PM
~300 patients
28 days

- Primary efficacy endpoint: Mean diurnal IOP on Day 28
- Two concentrations of PG324 vs. AR-13324 0.02% and latanoprost
- Trial design similar to registration trial for fixed-dose combination
  - 1-3 mmHg superiority vs. components previously accepted by FDA
- Trial starts early 2014
- Data expected mid-2014
Key Milestones

- **Early-2014: PG324**
  Start Phase 2b clinical trial

- **Mid-2014: AR-13324**
  Start Phase 3 registration trials

- **Mid-2015: AR-13324**
  Efficacy results from Phase 3 expected

- **Mid-2016: AR-13324**
  NDA filing expected

- **Mid-2014: PG324**
  Results from Phase 2b expected

- **Mid-2015: PG324**
  Phase 3-prep
Aerie – Next Generation in Glaucoma Therapies

• Large Market Opportunity - $4.5B US/EU/JP Market
  - Significant unmet needs - 50% of patients require more than one drug
  - No PGA fixed-combination products approved in the US

• Proprietary, Differentiated First-in-Class Glaucoma Pipeline
  - Both ROCK & NET inhibition - First new MOAs in two decades
  - Potential additional new MOA – lowering of EVP

• AR-13324: Novel Dual-Action, Once-Daily Therapy
  - Phase 3 expected to begin mid-2014; efficacy data expected mid-2015
  - NDA filing expected by mid-2016

• PG324: Breakthrough Triple-Action, Once-Daily Therapy
  - Fixed combination of AR-13324 and PGA latanoprost
  - Phase 2b data expected mid-2014; Phase 3 readiness expected mid-2015

• All Products Developed Internally - Own Class & Compounds
  - Patent protection through at least 2030 in the US
  - All rights retained with no partnerships