

Today's Changes	Annual EPS	Annual Revenue	Rating/Target
	2014E \$(1.43) from \$(1.92)	No changes	No changes
	2015E \$(1.46) from \$(2.05)		

## Aerie Pharmaceuticals

AERI : NASDAQ : US\$15.32

**BUY****Target: US\$28.00**

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### COMPANY STATISTICS:

Forecast Return:	83%
Shares Out (M):	23.7
Market Cap (M):	US\$363.1
52-week Range:	US\$10.25 - 27.15

### EARNINGS SUMMARY:

FYE Dec	2013A	2014E	2015E
Revenue:	0.0	0.0	0.0
EPS:	(1.60)	(1.43)	(1.46)

Revenue:	Q1	-	0.0A	-
	Q2	-	0.0	-
	Q3	0.0	0.0	-
	Q4	0.0	0.0	-
Total		0.0	0.0	0.0
EPS:	Q1	-	(0.28)A	-
	Q2	-	(0.33)	-
	Q3	(0.46)	(0.35)	-
	Q4	(0.62)	(0.37)	-
Total		(1.60)	(1.43)	(1.46)

### SHARE PRICE PERFORMANCE:

Aerie Pharmaceuticals, Inc. (NASDAQ: AERI)  
 May 12, 2014 Open: 14.930 High: 15.930 Vol: 67,031  
 Time: 16:00 Last: 15.320 Low: 14.620 Chg: 0.470 (+3.17%) ▲



Source: Interactive Data Corporation

### COMPANY DESCRIPTION:

AERI is a clinical-stage pharmaceutical company focused on the treatment of glaucoma (one of the largest segments in the global ophthalmic market) and other eye diseases. Its product candidates are the dual-action AR-13324 and triple-action PG324.

All amounts in US\$ unless otherwise noted.

### Life Sciences -- Biotechnology

## Q1/14: ROCLATAN PH2B AHEAD OF SCHEDULE, POISED FOR SUCCESS IN JUST A FEW MONTHS

### Investment recommendation

Reiterate BUY, \$28 target on AR-13324's potential in open-angle glaucoma as a monotherapy and as part of PG324 combotherapy. We believe AR-13324, a novel ROCK/NET inhibitor, may become one of the most versatile drugs for open-angle glaucoma. We think Ph3 AR-13324 data and Ph2 PG324 data expected in 2015 will be positive, showing good efficacy and safety. We estimate \$600M peak sales across both drugs. Our \$28 target is based on a pNPV analysis.

### Investment highlights

- **Q1 EPS \$(0.28) vs consensus \$(0.29) and our estimates \$(0.43).** \$65.1M in cash is expected to fund Rhopressa Ph3 through NDA and Roclatan through Ph2b.
- **Roclatan Ph2b enrolled ahead of schedule, data now expected June/July 2014.** We think at least one of two combos of '324 and latanoprost will show IOP lowering of >1mm HG beyond the trial's '324 or latanoprost arms, with good safety and tolerability. We think the trial has positive preclinical precedent as well as supportive '324 Ph2 monotherapy data.
- **Rhopressa Ph3 trials on schedule for Q3/14 start, top-line data mid-2015.** There will be two registration trials, ROCKET-1 and ROCKET-2. '2 will have qd and bid arms, and the bid arm will have 12 month treatment to meet FDA safety package requirements. A separate Canadian safety study will complete the FDA-required safety package. Total enrollment across the three trials will be ~1,300 patients.

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## MILESTONES AND TRIAL DESIGN

**Figure 1: AERI upcoming milestones**

Time	Milestone
Early Q3/14	Rhopressa start Ph3 registration trials
June or July/14	Roclatan Ph2b results
Mid-2015	Rhopressa Ph3 efficacy results
Mid-2015	Roclatan Ph3 prep
Mid-2016	Rhopressa NDA filing expected

Source: Canaccord Genuity and company reports

**Figure 2: Ph2B Roclatan Trial Design**

Ph2B Roclatan Trial Design	
Enrollment	~300 patients
Primary Endpoint	Mean diurnal IOP on Day 28
Cohort 1	Roclatan 0.01%
Cohort 2	Roclatan 0.02%
Cohort 3	Rhopressa 0.02%
Cohort 4	Latanoprost
Expectations	Design similar to registration trial for fixed-dose combo 1-3 mmHg superiority vs. components already accepted by FDA
Timing of data	Late June or Early July 2014

Source: Canaccord Genuity and company reports

**Figure 3: Rhopressa Ph3 Trial Design**

Rhopressa Registration Trial Design	
<b>Rocket 1</b>	Rhopressa 0.02% QD (N~200)
<b>90-Day Efficacy Registration Trial</b>	Timolol BID (N~100)
<b>Rocket 2</b>	Rhopressa 0.02% QD (N~230)
<b>One Year Safety (3 mo. Interim efficacy) Registration Trial)</b>	Rhopressa 0.02% BID (N~230)
	Timolol BID (N~230)
<b>Rocket 3</b>	Rhopressa 0.02% QD (N~90)
<b>One year Safety-Only--Canada</b>	Rhopressa 0.02% BID (N~90)
	Timolol BID (N~60)

Source: Canaccord Genuity and company reports

13 May 2014

Figure 4: AERI P&amp;L

	2012A	2013A	Q1/14A	Q2/14E	Q3/14E	Q4/14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
AR-13324	-	-	-	-	-	-	-	-	-	14.6	85.0	164.6	247.4
PG324	-	-	-	-	-	-	-	-	-	-	3.6	36.6	79.3
<b>Product revenues</b>	-	-	-	-	-	-	-	-	-	<b>14.6</b>	<b>88.6</b>	<b>201.2</b>	<b>326.7</b>
Grant revenue	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Total revenues</b>	-	-	-	-	-	-	-	-	-	<b>14.6</b>	<b>88.6</b>	<b>201.2</b>	<b>326.7</b>
Cost of goods sold	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Gross Profit</b>	-	-	-	-	-	-	-	-	-	<b>14.6</b>	<b>88.6</b>	<b>201.2</b>	<b>326.7</b>
R&D expense	9.3	12.3	5.4	4.5	5.0	5.5	20.4	20.0	25.0	25.3	25.5	25.8	26.0
SG&A expense	5.0	9.8	3.6	3.3	3.5	3.5	13.9	15.0	17.0	32.0	33.6	35.3	37.0
Other operating expense	0.7	0.4	-	-	-	-	-	-	-	-	-	-	-
<b>Total operating expense</b>	<b>15.0</b>	<b>22.6</b>	<b>9.0</b>	<b>7.8</b>	<b>8.5</b>	<b>9.0</b>	<b>34.2</b>	<b>35.0</b>	<b>42.0</b>	<b>57.3</b>	<b>59.1</b>	<b>61.0</b>	<b>63.1</b>
<b>Operating income</b>	<b>(15.0)</b>	<b>(22.6)</b>	<b>(9.0)</b>	<b>(7.8)</b>	<b>(8.5)</b>	<b>(9.0)</b>	<b>(34.2)</b>	<b>(35.0)</b>	<b>(42.0)</b>	<b>(42.6)</b>	<b>29.5</b>	<b>140.2</b>	<b>263.6</b>
Net Interest/Investment income	-	0.0	-	-	-	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(interest expense)	-	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1
Other non-operating income (expense)	(0.7)	(8.9)	2.3	-	-	-	-	-	-	-	-	-	-
Interest and other, Net	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Pre-tax income</b>	<b>(15.7)</b>	<b>(31.4)</b>	<b>(6.7)</b>	<b>(7.8)</b>	<b>(8.5)</b>	<b>(9.0)</b>	<b>(34.2)</b>	<b>(34.9)</b>	<b>(41.9)</b>	<b>(42.6)</b>	<b>29.6</b>	<b>140.2</b>	<b>263.7</b>
Income tax expense (benefit)	-	-	-	-	-	-	-	-	-	-	-	-	-
<b>Net income (loss)</b>	<b>(15.7)</b>	<b>(31.4)</b>	<b>(6.7)</b>	<b>(7.8)</b>	<b>(8.5)</b>	<b>(9.0)</b>	<b>(34.2)</b>	<b>(34.9)</b>	<b>(41.9)</b>	<b>(42.6)</b>	<b>29.6</b>	<b>140.2</b>	<b>263.7</b>
<b>Basic EPS</b>	<b>(0.93)</b>	<b>(1.60)</b>	<b>(0.28)</b>	<b>(0.33)</b>	<b>(0.35)</b>	<b>(0.37)</b>	<b>(1.43)</b>	<b>(1.46)</b>	<b>(1.74)</b>	<b>(1.76)</b>	<b>1.21</b>	<b>5.72</b>	<b>10.71</b>
Basic shares outstanding	16.8	19.6	23.7	23.8	24.0	24.1	23.9	24.0	24.1	24.3	24.4	24.5	24.6

Source: Canaccord Genuity estimates and company reports

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**Figure 5: AERI pNPV analysis**

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**Product Development**

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Drug name	Indication	Status	Launch	Success	Sales (US\$m)	Royalty	Profitability	NPV (US\$)
AR-13324	Open angle glaucoma	Phase 3	2017.5	70%	380.7	95%	85%	19.82
PG324	Open angle glaucoma	Phase 2	2018.5	55%	325.0	95%	85%	8.48
Total								28.30

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Source: Canaccord Genuity estimates and company reports

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**Investment risks**

Clinical risk -- AR-13324's planned Phase 3 program and or PG324's Phase 2 and 3 programs may not be successful. While we believe there is strong positive precedent data for AR-13324 from Phase 2 studies, there is a chance the planned Phase 3 trial will not be successful.

Regulatory risk -- FDA may not approve AR-13324 or PG234. There is no guarantee that FDA will approve AR-13324 or PG324 even if they showed expected levels of IOP lowering. Should FDA's understanding of the relationship between IOP lowering and loss of visual acuity change, the agency may want additional measures of benefit to grant approval. Further, clinical trials could yield some new safety signal that could be of concern.

Competitive risk -- There are a number of other current, well-established classes of glaucoma therapy on the market. Other glaucoma drugs, which utilize different mechanisms to treat the disease, have all been approved for years, if not decades; ophthalmologists have had significant experience treating patients with these medications, and have significant comfort with their efficacy and side effect profiles. As a result, ophthalmologists may continue to preferentially prescribe these drugs despite any potentially superior therapeutic profile of AR-13324 or PG324.

Commercialization/reimbursement risk -- Most current glaucoma therapies are generics, and are available relatively cheaply compared to AERI's intended pricing for AR-13324 and PG324; therefore, there is no guarantee AERI will be able to secure reimbursement for these drugs. Most (but not all) glaucoma medications are available in generic form in the US for <\$1 per day in treatment cost. Branded glaucoma therapies that cost between \$2 and \$3/day (the commercial plan for AR-13324 and PG324) are still able to secure reimbursement and meaningful market share, although many are restricted to second-line use with step-edits. We think this will also be the case of the AERI drug despite a significant premium to the existing generics, especially given our predicted superior therapeutic profile.

Financial risk -- AERI's current cash position will not extend through commercialization of AR-13324. AERI has current pro forma assets of \$55M, which we estimate will cover operating expenses through NDA filing of AR-13324, expected in H1/16. This includes the cost of the Phase 3 for AR-13324 and the planned Phase 2b trial of PG324. However, unless AERI secures a significant amount of non-dilutive financing through establishment of commercial partnership, it is unlikely to have cash to cover operating expenses through the AR-13324 launch or for additional Phase 3 development of PG324. Aerie may raise money through the issuance of additional equity.

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**Site Visit:**

An analyst has visited Aerie Pharmaceuticals' material operations in Bedminster, NJ. No payment or reimbursement was received from the issuer for the related travel costs.

**Price Chart:\***

Market Price				Target Price			
Date	Analyst	Rating	Target Price	Date	Analyst	Rating	Target Price
1) 11/19/2013	Baral	Buy	19.00	2) 01/13/2014	Baral	Buy	28.00

\*Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

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(as of 31 March 2014)

Coverage Universe			IB Clients	
Rating	#	%	%	
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Speculative Buy	43	4.4%	55.8%	
Hold	317	32.1%	13.2%	
Sell	45	4.6%	4.4%	
	988*	100.0%		

\*Total includes stocks that are Under Review

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