

	Annual EPS	Annual Revenue	Rating/Target
Today's Changes	2013E \$(1.27) from \$(1.06) 2014E \$(1.38), no change	No change	No change

Aerie Pharmaceuticals

AERI : NASDAQ : US\$13.60

BUY**Target: US\$19.00**

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COMPANY STATISTICS:

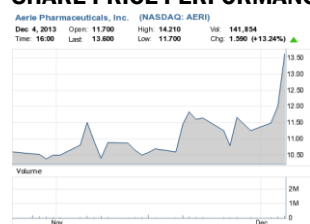
Forecast Return:	40%
Shares Out (M):	22.3
Market Cap (M):	US\$303.3
52-week Range:	US\$10.25 - 14.21

EARNINGS SUMMARY:

FYE Dec	2013E	2014E	2015E
Revenue:	0.0	0.0	0.0
EPS:	(1.02)	(1.38)	(1.47)

Revenue:	Q1	-	0.0	-
	Q2	-	0.0	-
	Q3	0.0A	0.0	-
	Q4	0.0	0.0	-
Total		0.0	0.0	0.0
EPS:	Q1	-	(0.31)	-
	Q2	-	(0.33)	-
	Q3	(0.46)A	(0.36)	-
	Q4	(0.28)	(0.38)	-
Total		(1.27)	(1.38)	(1.47)

SHARE PRICE PERFORMANCE:



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

Q3/13: EYES ON FINAL AR-13324 PH3 TRIAL DESIGN; WE SEE MINIMAL ENROLLMENT HURDLE AND SIGNIFICANT POTENTIAL UPSIDE

Investment recommendation

Reiterate BUY, \$19 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 \$19 target is based on a pNPV analysis.

Investment highlights

- AERI reported Q3 EPS of \$(10.81) compared with consensus of \$(0.38) and our estimate of \$(0.28). We note the share count AERI used to calculate Q3 EPS reflected pre-IPO capital structure of 1M shares outstanding; in our model we calculate Q3 EPS at \$(0.46).
- We expect no delay, and perhaps even early enrollment completion, in Ph2b PG324 study in Q1/14 and the two Ph3 AR-13324 studies in Q2/14 given short duration of trial and large glaucoma population. AERI indicated to us that its interaction with the FDA thus far suggests minimal change to its current proposed trial design (Fig. 1).
- We think there may be significant upside to the stock as we currently model a conservative US glaucoma population of 2.5M with a diagnosis rate of 55%. We think the actual glaucoma US population may be to the tune of 3.5M and the diagnosis rate may be much higher given the growth of eye care professionals in recent years. As such, with positive data, we think AR-13324 and PG324 could surpass our current combined peak sales estimate of \$600M.

Figure 1: Pivotal Ph3 trial design – Canaccord Genuity projection

	Pivotal Phase 3 – Canaccord Genuity projection
NCT ID	TBA
Design	Randomized, placebo controlled, double blind
Enrollment	At least 1200 subjects
Dosing	AR-13324 Ophthalmic Solution 0.01% and 0.02% and latanoprost ophthalmic solution
Key inclusion criteria	<ul style="list-style-type: none"> • Diagnosis of open angle glaucoma (OAG) or ocular hypertension (OHT). • Unmedicated (post-washout, p.r.n.) IOP \geq 24 mm Hg in one or both eyes at 08:00 hours, \geq 21 mm Hg at 10:00, 12:00 and 16:00 hours on post-washout measurement (Visit 1). • Corrected visual acuity in each eye \geq 1.0 logMAR or better by ETDRS in each eye (equivalent to 20/200).
Key exclusion criteria	<ul style="list-style-type: none"> • Glaucoma: pseudoexfoliation or pigment dispersion component, history of angle closure or narrow angles. Note: Previous laser peripheral iridotomy is NOT acceptable. • Intraocular pressure $>$ 36 mm Hg • Previous glaucoma intraocular surgery or glaucoma laser procedures in study eye(s, e.g., laser trabeculoplasty). • Ocular medication of any kind within 30 days of Visit 0, with the exception of a) ocular hypotensive medications (which must be washed out according to the provided schedule), b) lid scrubs (which may be used prior to, but not after Visit 0) or c) lubricating drops for dry eye (which may be used throughout the study). • Clinically significant ocular disease (e.g. uveitis, severe keratoconjunctivitis sicca) which might interfere with the study, including glaucomatous damage so severe that washout of ocular hypotensive medications for one month is not judged safe (i.e., cup-disc ratio $>$ 0.8). • Central corneal thickness greater than 600 μm.
Primary endpoint	Intraocular pressure at 3 months
Secondary endpoint	Safety at 12 months and visual acuity
Powering	TBA

Source: clinicaltrials.gov and Canaccord Genuity estimates

5 December 2013

Figure 2: AERI P&L

	2012A	H1/13A	Q3/13A	Q4/13E	2013E	Q1/14E	Q2/14E	Q3/14E	Q4/14E	2014E	2015E	2016E
AR-13324	-	-	-	-	-	-	-	-	-	-	-	-
PG324	-	-	-	-	-	-	-	-	-	-	-	-
Product revenues	-	-	-	-	-	-	-	-	-	-	-	-
Grant revenue	-	-	-	-	-	-	-	-	-	-	-	-
Total revenues	-	-	-	-	-	-	-	-	-	-	-	-
Cost of goods sold	-	-	-	-	-	-	-	-	-	-	-	-
Gross Profit	-	-	-	-	-	-	-	-	-	-	-	-
R&D expense	9.3	6.3	2.4	3.5	12.2	4.0	4.5	5.0	5.5	19.0	20.0	25.0
SG&A expense	5.0	3.4	3.3	3.0	9.7	3.3	3.3	3.5	3.5	13.6	15.0	17.0
Other operating expense	0.7	0.4	-	-	0.4	-	-	-	-	-	-	-
Total operating expense	15.0	10.1	5.7	6.5	22.3	7.3	7.8	8.5	9.0	32.6	35.0	42.0
Operating income	(15.0)	(10.1)	(5.7)	(6.5)	(22.3)	(7.3)	(7.8)	(8.5)	(9.0)	(32.6)	(35.0)	(42.0)
Net Interest/Investment income	-	-	-	-	0.0	-	-	-	-	0.0	0.0	0.0
(interest expense)	-	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.1	0.1
Other non-operating income (expense)	(0.7)	(0.3)	(5.1)	-	(5.4)	-	-	-	-	-	-	-
Interest and other, Net	-	-	-	-	-	-	-	-	-	-	-	-
Pre-tax income	(15.7)	(10.4)	(10.7)	(6.5)	(27.6)	(7.3)	(7.8)	(8.5)	(9.0)	(32.5)	(34.9)	(41.9)
Income tax expense (benefit)	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss)	(15.7)	(10.4)	(10.7)	(6.5)	(27.6)	(7.3)	(7.8)	(8.5)	(9.0)	(32.5)	(34.9)	(41.9)
Basic EPS	(0.93)	(0.55)	(0.46)	(0.28)	(1.27)	(0.31)	(0.33)	(0.36)	(0.38)	(1.38)	(1.47)	(1.76)
Basic shares outstanding	16.8	18.9	23.2	23.3	21.8	23.4	23.6	23.7	23.8	23.6	23.7	23.9

Source: Company reports and Canaccord Genuity estimates

Figure 3: AERI pNPV analysis

Product Development														
Drug name	Indication	Status	Launch	Years to Launch	Years to Peak	Success	Sales (US\$m)	Probability weighted Peak Sales (US\$m)	Royalty	Profitability	Probability weighted Peak Profit (US\$m)	Discount Factor	NPV (US\$)	
AR-13324	Open angle glaucoma	Phase 3	2017.5	4	9	65%	297.6	193.4	95%	85%	156.18	7.05	13.37	
PG324	Open angle glaucoma	Phase 2	2018.5	5	11	45%	290.8	130.9	95%	85%	105.69	11.01	5.79	
Total													19.16	

Source: Company reports and Canaccord Genuity estimates

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.

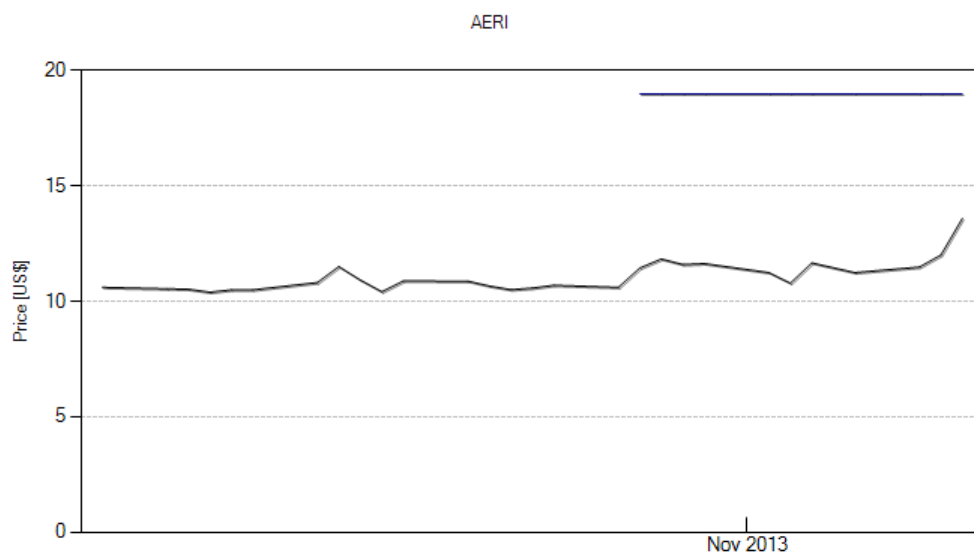
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Site Visit:

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				

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

Distribution of Ratings:

Global Stock Ratings
(as of 30 September 2013)

Rating	Coverage Universe		IB Clients	
	#	%		%
Buy	562	57.9%	37.7%	
Speculative Buy	47	4.8%	57.4%	
Hold	313	32.2%	11.2%	
Sell	47	4.8%	6.4%	
	971*	100.0%		

*Total includes stocks that are Under Review

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