Aerie Pharmaceuticals

AERI : NASDAQ : US$19.26

BUY

Target: US$28.00

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COMPANY STATISTICS:

Forecast Return:	45%
Shares Out (M):	23.3
Market Cap (M):	US$448.8
52-week Range:	US$10.31 - 21.99

EARNINGS SUMMARY:

FYE Dec		2013E	2014E	2015E
Revenue:		0.0	0.0	0.0
EPS:		(1.27)	(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

GLAUCOMA360 FIELD REPORT: FOCUS ON INNOVATION AND REIMBURSEMENT

Investment recommendation

Reiterate BUY, $28 price target on AR-13324 potential in open-angle glaucoma and potential BD interest in AERI. We think ROCK/NET inhibitor 13324 may become a leading drug for glaucoma. We think Ph2 comboTx PG324 data expected mid-2014 and Ph3 13324 data expected 2015 will be positive. Our pNPV based target of $28 is based on a peak sales estimate of $700M.

Investment highlights

- **ROCK inhibitor field thins but other mechanisms emerge.** We think the only remaining ROCK inhibitors in active development are AERI's Ph3 '324 and Amakem's Ph2 AMA0076 (bid, with potentially less red-eye tolerability issues). Other emerging drugs that are also promising include Ono's Ph2 FP/EP3 dual receptor agonist for ocular hypertension and Inotek's Ph2 trabodenoson, an adenosine receptor subtype A1 agonist that also targets the trabecular meshwork and may have Ph2b data (PG comboTx) in Q4/14.
- **Big pharma BD efforts still focused on glaucoma, but internal pipelines seem light.** The conference featured a panel with Alcon/ Novartis, Allergan, and Bausch & Lomb/Valeant. We think all have active BD efforts in glaucoma, especially since their internal pipelines are likely limited. Only Valeant has a NO-donating PG drug in Ph3. BD for all three is focused on innovative, differentiated new drugs with better drug delivery.
- **Strong focus on reimbursement, seen as critical for new glaucoma drugs' success.** Given the patient demographics, reimbursement (esp. by CMS) is key for a drug's potential. Cost/benefit and pharmacoecomic analyses will be key for reimbursement.

Figure 1: 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 2: 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	70%	380.7	266.5	95%	85%	215.18	6.66	19.47
PG324	Open angle glaucoma	Phase 2	2018.5	5	11	55%	325.0	178.8	95%	85%	144.35	10.41	8.36
										Total			**27.84**

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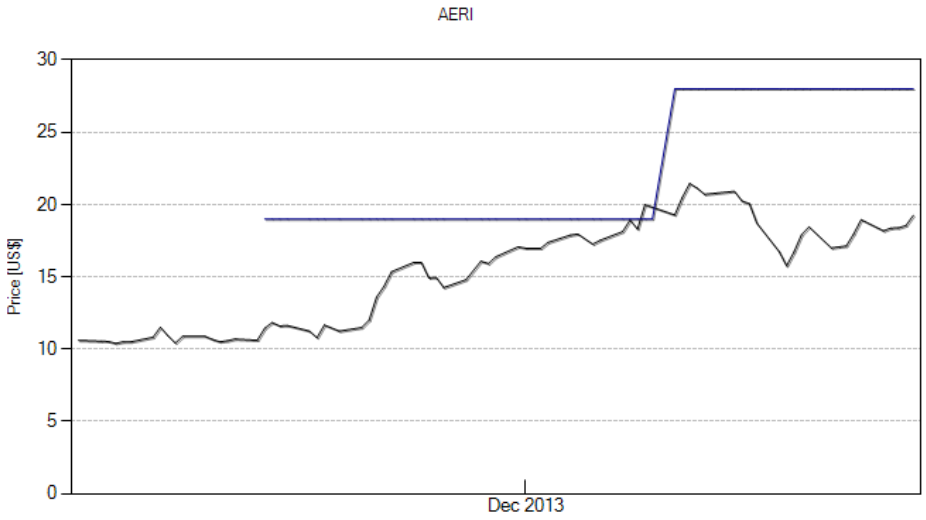
Site Visit: An analyst has visited Aerie Pharmaceuticals' material operations in Bedminster, NJ. No payment or reimbursement was received from the issuer for the related travel costs.

Price Chart:*



	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 December 2013)

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Buy	564	57.0%	38.1%
Speculative Buy	47	4.7%	42.6%
Hold	325	32.8%	11.4%
Sell	50	5.1%	6.0%
	990	100.0%	

*Total includes stocks that are Under Review

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