Aerie Pharmaceuticals

AERI : NASDAQ : US$17.19

BUY

Target: US$40.00

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COMPANY STATISTICS:

Forecast Return:	132.8%
52-week Range:	10 - 27
Shares Out (M):	23.9
Market Cap (M):	US$410
Avg. Daily Vol. (000s):	376
Cash (M):	65
2014E Burn:	($35)
2015E Burn:	($46)
# Analysts:	4
Avg. Target:	38
# BUY:	4
Shares Short (M):	0.8
Days to Cover:	1.4

EARNINGS SUMMARY:

FYE Dec		2013A	2014E	2015E	2016E
EPS:		(1.42)	(1.47	(1.55)	(1.46)
EPS:	Q1	(4.33)	(0.20)A	-	-
	Q2	(0.27)	(0.39)A	-	-
	Q3	(0.42)	(0.44)	-	-
	Q4	(0.54)	(0.43)	-	-
Total		(1.42)	(1.47)	(1.55)	(1.46)

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 triple-action Rhopressa and quadruple-action Roclatan.

All amounts in US$ unless otherwise noted.

Life Sciences -- Specialty Pharmaceuticals

SEPT. 10 ANALYST DAY PREVIEW

Investment recommendation

At its upcoming analyst day in New York, Aerie plans to: 1) take a deeper dive into the Roclatan Ph2 data, with a focus on the Rhopressa component, as it demonstrated unprecedented IOP lowering effects; 2) offer an update on Rhopressa Ph3 enrollment rates; 3) give insights into commercialization strategies; and 4) provide ex-US partnering status.

Investment highlights

In the Ph2b, Rhopressa was actually non-inferior to latanoprost, which is known to be more potent than timolol – the active comparator for the Rhopressa P3 trials (3 studies with a total n=1,300). The percent of patients who reached <16mmHg IOP were: 1) 50% of Roclatan patients, 2) 21% of Rhopressa patients, and 3) 18% of latanoprost patients. And all the patients who got to that 16mmHg threshold had about the same entry pressure – 24.5mmHg. While the reduction was anticipated for the Roclatan arm, it was impressive that Rhopressa also dropped pressures over 10mmHg, whereas in previous studies it had only been lowering pressures in the 6-8mmHg range. Both drugs also showed much less variability than latanoprost. Additionally, even in patients with high IOPs (~28mmHg), Rhopressa had a mean pressure drop of 12mmHg, an outcome that no other non-PGA has yet been able to show.

On the commercialization front, Aerie has been in active conversations with ~20 companies in the last month alone – for ex-US rights. Many expressed strong interests in the clinical data and have signed Confidential Disclosure Agreements. Thus we look forward to obtaining more clarity on potential partnerships at the event.

Valuation/risks

Our one-year forward price target of $40 is derived by using a 20x multiple of our 2020 EPS estimate of $6.81 and discounting back at 25% for 5.5 years. Risks include: failure of either Rhopressa or Roclatan in Phase 3 trials and/or failure to gain FDA on either drug.

Figure 1: Summary Aerie P&L model

($ In millions, except per share amount)

Year End: December 31	2012	2013	1Q14	2Q14E	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E
Rhopressa	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$25.5	$135.1	$243.6	$349.6	$455.5	$521.7
Roclatan	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$31.9	$126.8	$269.1	$356.8	$494.5
Total Revenue	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$0.0**	**$25.5**	**$167.0**	**$370.4**	**$618.6**	**$812.3**	**$1,016.2**
Gross Profit	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$22.9	$150.3	$333.4	$556.8	$731.0	$914.6
Gross Margin										*90.0%*	*90.0%*	*90.0%*	*90.0%*	*90.0%*	*90.0%*
SG&A	$5.0	$9.9	$3.6	$5.2	$5.0	$5.0	$18.8	$16.0	$17.0	$50.0	$65.0	$74.8	$86.0	$90.3	$94.8
R&D	9.3	12.3	5.4	6.7	8.0	8.0	28.0	40.0	45.0	47.3	49.6	52.1	54.7	52.0	49.4
Adj. Operating Income	**(14.3)**	**(32.2)**	**(9.0)**	**(11.8)**	**(13.0)**	**(13.0)**	**(46.8)**	**(56.0)**	**(62.0)**	**(74.3)**	**29.5**	**140.2**	**263.6**	**370.9**	**466.9**
Adj. Operating Margin											*17.7%*	*37.9%*	*42.6%*	*45.7%*	*45.9%*
Non-Op	(0.7)	(8.6)	2.3	0.0	0.1	0.1	2.4	1.0	1.0	1.0	1.0	1.0	1.0	1.0	1.0
Tax Rate									0.0%	0.0%	0.0%	0.0%	0.0%	25.0%	38.0%
Adj. Net Income	(15.3)	(27.8)	(4.8)	(9.4)	(10.6)	(10.6)	(35.3)	(46.0)	(51.0)	(61.3)	44.5	157.2	282.6	298.9	310.1
Net Margin	*0%*	*0.0%*	*0%*								*26.7%*	*42.4%*	*45.7%*	*36.8%*	*30.5%*
GAAP EPS (diluted)	$0.00	($1.23)	($0.28)	($0.49)	($0.54)	($0.53)	($1.85)	($1.86)	($1.20)	($1.06)	$0.73	$3.44	$6.38	$6.66	$6.86
Adjusted EPS (diluted)	**$0.00**	**($1.42)**	**($0.20)**	**($0.39)**	**($0.44)**	**($0.43)**	**($1.47)**	**($1.55)**	**($1.46)**	**($1.52)**	**$1.09**	**$3.83**	**$6.81**	**$7.13**	**$7.33**
Diluted Shares (M)	0.0	19.6	23.7	23.9	24.1	24.4	24.0	29.6	34.9	40.3	40.7	41.1	41.5	41.9	42.3
Year-over-Year Growth															
Rhopressa											430%	80%	44%	30%	15%
Roclatan												298%	112%	33%	39%
Total Revenue											*556%*	*122%*	67%	31%	25%
Gross Profit											*556%*	*122%*	67%	31%	25%
SG&A			*146%*	*172%*	*52%*	*56%*	*91%*	*(15%)*	*6%*	*194%*	*30%*	*15%*	15%	5%	5%
R&D			*70%*	*115%*	*233%*	*122%*	*128%*	*43%*	*13%*	*5%*	*5%*	*5%*	5%	-5%	-5%
Operating Income												*375%*	88%	41%	26%
Net Income												*253%*	80%	6%	4%
Adj. EPS												***250%***	***78%***	***5%***	***3%***

Source: Company reports and Canaccord Genuity estimates

INVESTMENT RISKS

Clinical risk – Rhopressa's and Roclatan's Phase 3 programs may not be successful. While we believe there is strong positive precedent data for both from each of the respective Phase 2 studies, there is always a chance of failure in Phase 3. The Phase 2 trials only measured efficacy and safety at one month, but the Phase 3s will go out to three months for efficacy and one year for safety. In addition, a previous Aerie drug candidate showed roll-off of effect between month 1 and 3. However, we believe this older drug was more highly specific to ROCK inhibition than Rhopressa, which has low-level PKC inhibition activity as well. The PKC pathway may compensate for ROCK-mediated IOP lowering; therefore inhibiting both should result in sustained benefit. Given almost no systemic exposure with Rhopressa and Roclatan as eye drops, we expect continued clean safety, even with longer treatment duration in the upcoming Phase 3 trials versus the Phase 2.

Regulatory risk – FDA may not approve Rhopressa or Roclatan, as the agency is inherently unpredictable – even if the Phase 3 trials look successful on the surface. Should the FDA's interpretation of the relationship between IOP lowering and loss of visual acuity change, the agency may want additional measures of benefit to grant approval. We deem this highly unlikely given there have been many glaucoma drugs approved under the current and planned paradigm. Further, clinical trials could yield some new safety signal that could be of concern to the agency.

Competitive risk – There are a number of other current, well-established classes of glaucoma therapy on the market that clinicians have significant experience with; a number of other approved glaucoma drugs utilize different mechanisms to treat the disease. All of these drugs have 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 Rhopressa or Roclatan.

Commercialization/reimbursement risk – As we mentioned previously, most current glaucoma therapies are generics, and are available relatively cheaply compared to Aerie's intended pricing for Rhopressa ($110/month is our assumption) and Roclatan ($135/month is our assumption); therefore, there is no guarantee Aerie will be able to secure reimbursement for these drugs. Most (but not all) glaucoma medications are available in generic form in the US for <$30 per month. Branded glaucoma drugs like Lumigan and Alphagan are still able to secure reimbursement and meaningful market share, although many are restricted to second-line use with step-edits. Whether this ends up also being the case with Aerie will depend on the strength of the efficacy data – and whether Aerie is able to show evidence of disease modification.

Financial risk – Aerie's current cash position will last until mid-2016. While not really a risk per se, we have assumed two additional capital raises in our model – one in Q4 2014 and one in 2017 prior to the launch of Rhopressa. We do not factor in any upfront payments from potential partnerships from ex-US markets. And an inability to raise enough capital to extend operations until profitability would present a risk.

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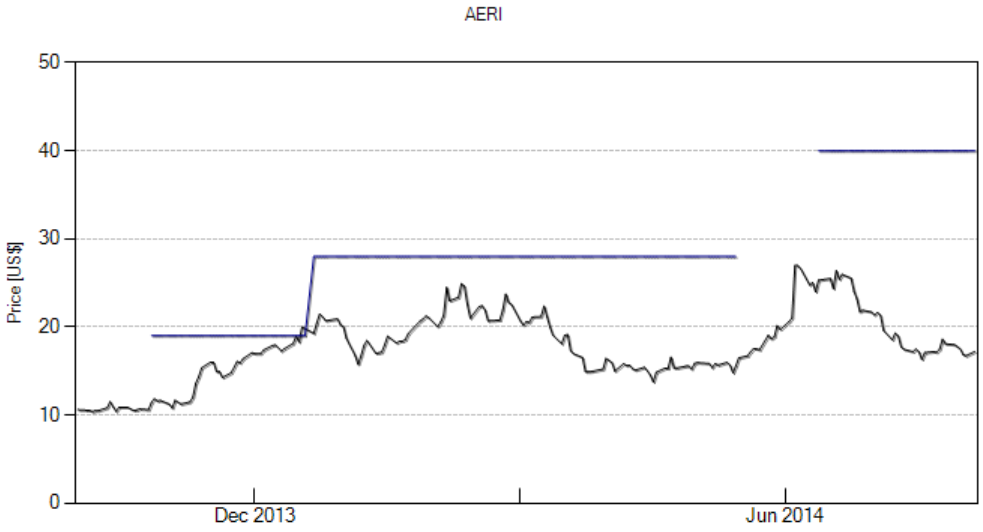
Site Visit: An analyst has visited Aerie Pharmaceuticals' material operations in Bedminster, NJ. No payment or reimbursement was received from the issuer for the related travel costs.

Price Chart:*



	Date	Analyst	Rating	Target Price		Date	Analyst	Rating	Target Price
1)	11/19/2013	Baral	Buy	19.00	3)	06/06/2014	Research	Suspended	
2)	01/13/2014	Baral	Buy	28.00	4)	07/03/2014	Davis	Buy	40.00

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

Distribution of Ratings:
Global Stock Ratings
(as of 3 July 2014)

	Coverage Universe		IB Clients
Rating	#	%	%
Buy	602	61.2%	38.2%
Speculative Buy	49	5.0%	55.1%
Hold	290	29.5%	13.1%
Sell	41	4.2%	7.3%

984	100.0%

*Total includes stocks that are Under Review

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Aerie Pharmaceuticals	1A, 2, 3, 5, 7

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