

**Annual EPS** 

**Today's Changes** 2014E (\$1.47) from (\$1.25)

2015E (\$1.55) from (\$1.38)

# **Aerie Pharmaceuticals**

AERI: NASDAQ: US\$17.18

**Target: US\$40.00** 

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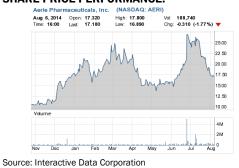
# **COMPANY STATISTICS:**

Forecast Return:	132.8%
52-week Range:	10 - 27
Shares Out (M):	23.9
Market Cap (M):	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	-0.20A		
	Q2	-0.27	-0.39A		
	Q3	-0.42	-0.44		
	Q4	-0.54	-0.43		
Total		-1.42	-1.47	-1.55	-1.46

# SHARE PRICE PERFORMANCE:



## **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

# Q2: ONE OF BEST SMALL CAPS

#### **Investment recommendation**

Aerie announced Q2 non-GAAP EPS of (\$0.39), a penny below our estimate of (\$0.38). While numbers matter little for an R&D driven story, we still expect cash burn to accelerate slightly as both Rhopressa and Roclatan enter Ph3 (a good thing). Aerie has \$57M in cash that should hold it until mid-2016, but we've modeled an equity raise in 2015.

## **Investment Highlights**

New news from the CC was that non-inferiority was shown between Rhopressa and latanoprost in the Roclatan Ph2b, which was even better than Rhopressa's own P2b study. Hence, we feel even better about a robust positive P3 outcome in mid-2015.

At its Sept. 10 analyst day, Aerie will take a deeper dive into the Ph2 data and gave several teasers on the Q2 call suggesting even greater enthusiasm – excitement that is trickling into the investigator community and bodes well for rapid enrollment in all of its ongoing and planned Ph3 trials on both drugs.

# Valuation/risks

Management more than adequately addressed questions responsible for the recent stock sell-off. We thus believe such concerns will soon be mitigated, as investors see the true value of the stock. 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.

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# **INVESTMENT THESIS**

Aerie has two drugs about to enter Phase 3 for glaucoma and we like the prospects of both, and what they could mean for the stock, for several reasons:

- 1. **Predictive Phase 2s**. Both have shown impressive Phase 2 data and in glaucoma, Phase 2 has been highly predictive of Phase 3. One interesting factoid is that all 13 glaucoma drugs that successfully completed Phase 2 also met with success in Phase 3 and were also eventually FDA approved. Hence we think Aerie has already significantly de-risked the story.
- 2. Excellent efficacy beat market leader in a head-to-head. On June 25, Aerie released the Roclatan Phase 2 trial. It showed about an 8.5 mmHG drop in Intra-Ocular Pressure (IOP) at Day 29, which is one of the highest drops ever seen with a glaucoma drug. In addition, it beat the latanaprost-only arm by 1.6-3.2 mmHg differences that were statistically significant at each time point. Latanoprost (now generic but was Pfizer's branded Xalatan) is the most widely used glaucoma drug and usually first-line therapy for patients.
- Long-lived assets. Because Rhopressa is a New Chemical Entity (NCE) it will have a
  very long patent/exclusivity life. The same would apply to Roclatan because it is simply
  a combination of Rhopressa and Xalatan (now generic as Latanoprost).
- 4. **Unique mechanism of action**. Even though Rhopressa is a single molecule, it works on the three different systems that contribute to glaucoma and ultimately end up damaging the optic nerve. This creates the potential to slow the course of the disease (although it is highly unlikely to have any sort of "disease modification" in the label).
  - a. Decreases fluid inflow/production ciliary processes
  - b. Increases fluid outflow relaxes the trabecular meshwork
  - c. Increases fluid outflow -opening the secondary drain (uveoscleral pathway)
- 5. **Huge market**. Depending on which estimate one uses, the worldwide glaucoma market is somewhere between \$4.5B and \$6B. And with an aging population and expansion into emerging markets, these figures are growing about 2% a year.
- 6. Limited competition. Although there are plenty of glaucoma drugs on the market, there are fewer and fewer actively promoted products. And relative to other pharmaceutical markets, there are very few in development. The current major players are Allergan, Valeant, and Alcon.
- 7. Multimodal therapy. Most glaucoma patients will eventually need multiple therapies due to the progressive nature of the disease; hence the need for combination treatments allows new treatment like Rhopressa and Roclatan to break into the market more easily.
- 8. **Poor compliance**. It is well known that glaucoma patients are poorly compliant with their eye drops since most need twice-daily eye drops of multiple medications. Hence the once-daily dosing of both Aerie's products is attractive.
- 9. **Small sales force**. Because the market is fairly concentrated and only a handful of physicians do the bulk of prescribing, Aerie will not need a large sales force (and



- hence low SG&A) to detail the products in the US if it chooses to. A sales force of 100-200 reps should be more than sufficient, in our view.
- 10. **Owns 100% of the rights**. Both products were invented by Aerie and hence are unencumbered by any royalties. That also leaves open the possibility for partnering in ex-US territories. This is one thing we always look for in a drug: inherently very high gross margins and because of the lower SG&A, very high operating margins, and by extension, tremendous EPS leverage because of the small share base.
- 11. **Plenty of cash.** At the end of June, Aerie had \$57M in cash on its balance sheet and it has stated that this would be sufficient to fund its operations through the middle of 2016. And although it does not look like Aerie NEEDS any cash for two years, we are never surprised when a company chooses to raise cash well before it needs to especially after successful Phase 2 data like Roclatan just showed.



# **VALUATION -- \$40 PRICE TARGET**

Because Aerie is unlikely to be profitable until 2018 at the earliest, we don't feel a DCF approach is warranted. Therefore as shown below, we simply use a discounted multiple approach. For fast-growing companies with new products with long life cycles, we think a 20x multiple off forward year earnings is appropriate. And we usually like to use a 25% discount rate on products not yet having completed Phase 3. Therefore, applying 20x to our 2020 EPS estimate and discounting it back 5.5 years (for a 12-month target) yields our \$40 price target. Because there are those who may disagree with our choice of multiples, years of earnings, and choice of discount rate, we present the sensitivity analysis in the two tables below.

Figure 1: Price target sensitivity analysis by year of EPS estimates

	2018	2019	2020	2021	2022
PE multiple	20.0x	20.0x	20.0x	20.0x	20.0x
EPS	\$1.09	\$3.83	\$6.81	\$7.13	\$7.33
Total	21.89	76.55	136.25	142.69	146.56
Discount Rate	25%	25%	25%	25%	25%
Discount Years	3.5	4.5	5.5	6.5	7.5
Price Target	\$10	\$28	\$40	\$33	\$27
Current price:	\$17.18	\$17.18	\$17.18	\$17.18	\$17.18
Return	(41.7%)	63.2%	132.4%	94.7%	60.0%

Source: CGI estimates

Figure 2: Price target sensitivity analysis by multiple and discount rate

2020 EPS:	\$6.81				Multi	ple		
Discount Period:	5.5		10.0x	15.0x	20.0x	25.0x	30.0x	35.0x
		10.0%	\$40	\$60	\$81	\$101	\$121	\$141
		15.0%	\$32	\$47	\$63	\$79	\$95	\$111
	Discount	20.0%	\$25	\$37	\$50	\$62	\$75	\$87
	Rate	25.0%	\$20	\$30	\$40	\$50	\$60	\$70
		30.0%	\$16	\$24	\$32	\$40	\$48	\$56
		35.0%	\$13	\$20	\$26	\$33	\$39	\$46
		40.0%	\$11	\$16	\$21	\$27	\$32	\$37

Source: CGI estimates



# **2Q RESULTS**

Figure 3: 2Q14 variance

Year end December 31	Actual	CGI	Variance	Consensus
Total Revenue	\$0	\$0	\$0	
G&A	5.2	4.0	1.2	
R&D	6.7	7.0	(0.3)	
Net Income	(9.4)	(9.1)	(0.3)	
Non-GAAP EPS	(\$0.39)	(\$0.38)	\$0.01	
Shares Out. (MM)	23.9	23.7	0.2	

Source: Company reports, CGI estimates

Figure 4: Changes to our estimates

(In millions \$, except EPS)		2014E			2015E			2016E			2017E			2018E	
Year end December 31	OLD	NEW	Δ	OLD	NEW	Δ	OLD	NEW	Δ	OLD	NEW	Δ	OLD	NEW	Δ
Rhopressa										\$25.5	\$25.5	\$0.0	\$135.1	\$135.1	\$0.0
Roclatan										\$0.0	\$0.0	\$0.0	\$31.9	\$31.9	\$0.0
Total Revenue										\$25.5	\$25.5	\$0.0	\$167.0	\$167.0	\$0.0
G&A	\$16.1	\$18.8	\$2.7	\$16.0	\$16.0	\$0.0	\$17.0	\$17.0	\$0.0	\$50.0	\$50.0	\$0.0	\$65.0	\$65.0	\$0.0
% of total revenues										196.3%	196.3%	0.0%	38.9%	38.9%	0.0%
R&D	\$31.4	\$28.0	(\$3.3)	\$40.0	\$40.0	\$0.0	\$45.0	\$45.0	\$0.0	\$47.3	\$47.3	\$0.0	\$49.6	\$49.6	\$0.0
% of total revenues										185.5%	185.5%	0.0%	29.7%	29.7%	0.0%
Tax Rate													0.0%	0.0%	0.0%
Net Income	(\$34.4)	(\$35.3)	(\$0.9)	(\$47.0)	(\$46.0)	\$1.0	(\$51.0)	(\$51.0)	\$0.0	(\$61.3)	(\$61.3)	\$0.0	\$44.5	\$44.5	\$0.0
Non-GAAP EPS	(\$1.25)	(\$1.47)	(\$0.22)	(\$1.38)	(\$1.55)	(\$0.18)	(\$1.48)	(\$1.46)	\$0.02	(\$1.54)	(\$1.52)	\$0.02	\$1.11	\$1.09	(\$0.01)
Shares Out. (MM)	27.5	24.0	(3.5)	34.1	29.6	(4.5)	34.5	34.9	0.4	39.8	40.3	0.4	40.2	40.7	0.4

Source: Company reports, CGI 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 AERI 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 galucoma 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 AERI's intended pricing for Rhopressa (\$110/month is our assumption) and Roclatan (\$135/month is our assumption); 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 <\$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** – AERI'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.

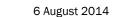




Figure 5: AERI P&L

(\$ In millions, except per share amount)

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Year End: December 31	2012	2013	1Q14	2Q14E		4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	
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, CGI estimates

6 August 2014

Figure 6: AERI Revenue Model

(In millions	)			
				TOTAL
ſ	Rhopressa	Roclatan	Other	REV ENUE
2017E	25.5			25.5
2018E	135.1	31.9		167.0
2019E	243.6	126.8		370.4
2020E	349.6	269.1		618.6
2021E	455.5	356.8		812.3
2022E	521.7	494.5		1,016.2
%Growth				
18E/17E	430.4%			555.6%
19E/18E	80.3%	297.8%		121.9%
20E/19E	43.5%	112.2%		67.0%

32.6%

38.6%

31.3%

25.1%

Source: Company reports, CGI estimates

21E/20E

22E/21E

30.3%

14.5%



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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:\*



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

Coverage Universe IB Clients										
Rating	#	%	"Market Chemis							
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%								

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

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