



September 25, 2014

## Aerie Pharmaceuticals, Inc.

### Latanoprostene bunod Phase III works; Shows AERI's Phase III can as well

**Our view:** Demonstrating non-inferiority to timolol is considered a relatively lower bar, which is why we also expect the Rhopressa Phase IIIs to be successful when they readout in 1H:15. The key will also be Phase III results from Roclatan, which could demonstrate superiority over a prostaglandin to establish the best efficacy in glaucoma. We continue to like AERI shares at current levels.

#### Key points:

- **What did Vesneo results show?** VRX and Nicox reported positive Phase III results in patients with glaucoma. The APOLLO and LUNAR studies compared Vesneo once per day to timolol twice per day, met the primary endpoint of non-inferiority, and showed a reduction in IOP of 7.5 to 9.1 mmHg from baseline between 2 and 12 weeks. The studies also showed superiority over timolol ( $p < 0.05$ ).
- **What have AERI's rho-kinase inhibitors shown?** Data is limited and it is not clear how the IOP lowering from baseline from the Vesneo study are being reported. Nevertheless a high level comparison, shows that AERI's Rhopressa and Roclatan also lower IOPs an average of 6 mmHg and 8-9 mmHg, respectively, in the Phase IIb results reported to date or a range of 6-7 mmHg and 8-9 mmHg vs. latanoprost of 7-8 mmHg between weeks 1-4 at various time points. More importantly, Roclatan beat latanoprost in the Phase IIb study.
- **What will AERI Phase IIIs show?** A prostaglandin is expected to do better than a beta blocker, e.g., timolol, so better efficacy should not be a surprise. AERI's Rhopressa Phase III uses timolol as a comparator and has a very good chance of demonstrating non-inferiority and possibly better efficacy. The Roclatan Phase III will use latanoprost as a comparator and if successful establish Roclatan as the most potent IOP lowering agent available. Phase IIb results already demonstrated as much.
- **Vesneo is new but more like a prostaglandin than not; Roclatan and Rhopressa are different.** Nicox partnered Vesneo (latanoprostene bunod), which is a nitric oxide donating prostaglandin F2-alpha analog, with Bausch & Lomb (VRX). Roclatan, which includes Rhopressa combined with latanoprost, and Rhopressa work by inhibiting rho kinase, norepinephrine transporter, and by lowering episcleral venous pressure, which makes the mechanism of action really unique.
- **Market is large.** Roughly 31M prescriptions are written annually for glaucoma drugs in the US. At branded drug pricing this is a \$3B+ market opportunity. Physician feedback consistently points to 10-20% of patients not responding to currently available drugs, which means an opportunity of at least \$300-600M for a new mechanism by itself in the US alone. VRX and Nicox expect to file an NDA in 2Q:15 with a launch forecast for 1H:16. We estimate AERI could file an NDA by mid-2016 followed by a launch in mid-2017 or sooner.

RBC Capital Markets, LLC

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### Outperform

#### Speculative Risk

NASDAQ: AERI; USD 18.27

#### Price Target USD 41.00

##### WHAT'S INSIDE

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<input type="checkbox"/> In-Depth Report	<input type="checkbox"/> Est. Change
<input type="checkbox"/> Preview	<input checked="" type="checkbox"/> News Analysis

#### Scenario Analysis\*

Current Price	Downside Scenario	Price Target	Upside Scenario
18.27	25.00 ↑ 37%	41.00 ↑ 124%	58.00 ↑ 217%

\*Implied Total Returns

#### Key Statistics

Shares O/S (MM):	23.2	Market Cap (MM):	424
Dividend:	0.00	Yield:	0.0%
		Avg. Daily Volume:	187,191

#### RBC Estimates

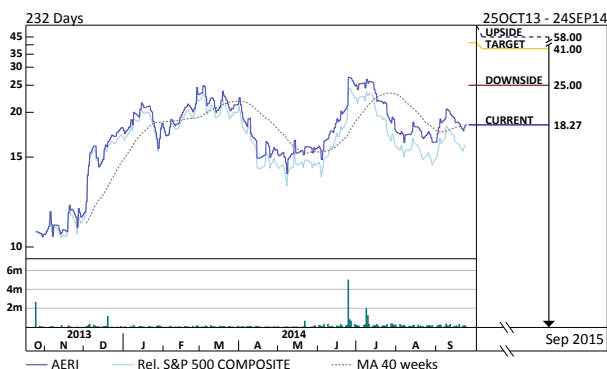
FY Dec	2013A	2014E	2015E	
Revenue	0.0	0.0	0.0	
EPS, Adj Diluted	(2.46)	(1.27)	(1.19)	
P/AEPS	NM	NM	NM	
Revenue	Q1	Q2	Q3	Q4
2013	0.0A	0.0A	0.0A	0.0A
2014	0.0A	0.0E	0.0E	0.0E
EPS, Adj Diluted				
2013	(0.41)A	(0.28)A	(10.81)A	(0.54)A
2014	(0.20)A	(0.39)A	(0.36)E	(0.32)E

EPS, Adj Diluted: Prior periods restated to show non-GAAP EPS  
All values in USD unless otherwise noted.



## Target/Upside/Downside Scenarios

Exhibit 1: Aerie Pharmaceuticals, Inc.



Source: Bloomberg and RBC Capital Markets estimates for Upside/Downside/Target

### Target price/ base case

We value AERI at \$41 per share, which includes US/EU sales of Rhopressa and Roclatan. We assign a 80% probability of success and a value of ~\$30 per share to the US and ~\$11 per share to the EU opportunity. We assume a US launch in 2017 and an EU launch in 2018. We forecast peak Roclatan sales of ~\$1.1B and ~\$0.7B and Rhopressa sales of ~\$0.6B and ~\$0.4B in the US and EU, respectively. Finally, we assume patent protection through 2030 and include a terminal value based on a discount rate of 15% and a growth rate of -50%.

### Upside scenario

Our upside scenario of \$58 includes ~\$41 per share in value for the US opportunity and ~\$18 per share in value for the EU opportunity. We forecast peak Roclatan sales of \$1.6B in the US and \$1.2B in the EU and Rhopressa sales of ~\$600MM in the US and ~\$570MM in the EU. We assign products in the pipeline a 80% probability of success, a discount rate of 15%, and a terminal growth rate of -50%.

### Downside scenario

Our downside scenario of \$25 assumes includes ~\$19 per share in value for the US opportunity and ~\$7 in value for the EU. We forecast peak Roclatan sales of \$1.1B in the US and ~\$660MM in the EU and Rhopressa sales of ~\$600MM in the US and ~\$440MM in the EU. We assign 50% probability of success, a discount rate of 15%, and a terminal growth rate of -50%.

## Investment summary

We believe AERI shares offer the potential for significant upside as both products in development, Rhopressa and Roclatan, use a new mechanism of action for the treatment of glaucoma, a blockbuster potential market. Rhopressa and Roclatan will enter Phase III trials based on positive Phase IIb data. Results from these and additional studies are expected 2014–2016. Millions of patients worldwide suffer from glaucoma, most need multiple medications, and we forecast peak sales of AERI's products at ~\$1B.

AERI owns 100% of the rights to Rhopressa and Roclatan worldwide and patent protection extends into 2030, which means the company is free to partner or be acquired. Given that ophthalmology remains an attractive therapeutic area and AERI's product candidates could have a convenient, one drop once per day efficacy and safety profile, progress through clinical and regulatory milestones, as well as a partnership, could all be upside catalysts.

### Potential catalysts for AERI shares

- **Phase III data for Rhopressa in 2015.** Important catalyst as positive data could lead to an NDA and MAA filing.
- **Phase III data for Roclatan in 2016.** Key catalyst as clean safety and efficacy beyond latanoprost could make Roclatan the first-line drug of choice.
- **Potential partnership for Rhopressa and Roclatan.** AERI owns worldwide rights to both product candidates and a partnership is likely after Phase III data.
- **Potential approvals and launches in 2017 in the US and in 2018 in the EU** following regulatory filings in 2016.

### Risks to our investment thesis

- **Pivotal Phase III and earlier-stage studies could fail.** Rhopressa must show non-inferiority to a comparator over a longer period and Roclatan must show a benefit in patients, which raises risk of failure.
- **AERI could fail to find a partner** for Rhopressa and Roclatan outside the US.
- **Sales ramp of Rhopressa and Roclatan could lag expectations** as clinicians fail to take up AERI's drugs, payers put up hurdles for reimbursing branded drugs, and cheaper generic drugs with other mechanisms hamper market penetration.



## Valuation

We value AERI at \$41 per share, which includes US/EU sales of Rhopressa and Roclatan. We assign a 80% probability of success and a value of ~\$31 per share to the US and ~\$11 per share to the EU opportunity. We assume a US launch in 2017 and an EU launch in 2018. We forecast peak Roclatan sales of ~\$1.1B and ~\$0.7B and Rhopressa sales of ~\$0.6B and ~\$0.4B in the US and EU, respectively. Finally, we assume patent protection through 2030 and include a terminal value based on a discount rate of 15% and a growth rate of -50%.

## Price target impediments

Our price target is dependent solely on the clinical, regulatory, and commercial success of Rhopressa and Roclatan. A Phase III study for Rhopressa and Roclatan are expected in 2014 and 2015 respectively, and failure to demonstrate efficacy or safety in one or both of these studies would be a significant setback. Furthermore, any setbacks in regulatory approvals in the US or EU, delay in launch, failure to secure a partnership outside the US for Rhopressa and Roclatan, increased competition, or other limitations to the market potential of these products either due to better efficacy and/or safety outcomes or pricing pressure due to the availability of generic drugs for glaucoma could negatively impact our valuation.

## Company description

Aerie Pharmaceuticals, Inc. is a biotechnology company targeting ophthalmic disorders specifically glaucoma, which is a blockbuster potential market. Sales of products targeting glaucoma totaled \$4.5B globally and more than 30 million prescriptions for glaucoma drugs were written in the US alone. AERI's drug candidates work by inhibiting rho-kinase and the norepinephrine transporter, a new mechanism of action, something not seen for glaucoma in nearly two decades. Rhopressa could enter Phase III trials in 2014 and Roclatan could enter Phase II trials in 2014 and Phase III trials in 2015. These drugs could be used as stand-alone agents for first- or second-line therapy or combined with existing agents.



## Aerie Pharmaceuticals - Income Statement FYE December 31

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(in MM; except per share)	2013A	1Q:14A	2Q:14A	3Q:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
<b>REVENUES</b>															
AR-13324									6.6	70.0	149.3	238.8	297.0	361.8	385.7
PG324										9.4	40.3	128.8	228.9	390.4	572.3
Product Sales									6.6	79.5	189.6	367.6	525.9	752.2	957.9
Royalties										12.5	31.0	55.6	74.5	99.7	119.0
Other															
<b>Total Revenues</b>									6.6	92.0	220.6	423.2	600.3	851.9	1,076.9
<b>EXPENSES</b>															
COGS									0.7	7.9	19.0	36.8	52.6	75.2	95.8
R&D	11.9	5.4	6.7	6.8	6.9	25.7	30.0	32.5	35.0	12.5	12.5	12.5	12.5	12.5	12.5
SG&A	10.3	3.6	5.2	5.3	5.4	19.5	22.3	25.0	30.0	37.5	45.0	73.5	105.2	150.4	191.6
Other															
<b>Total Expenses</b>	22.2	9.0	11.8	12.1	12.3	45.2	52.3	57.5	65.7	57.9	76.5	122.8	170.3	238.2	299.9
<b>Operating Income (Expense)</b>	(22.2)	(9.0)	(11.8)	(12.1)	(12.3)	(45.2)	(52.3)	(57.5)	(59.1)	(34.1)	(144.1)	(300.4)	(430.1)	(613.8)	(777.0)
<b>OTHER</b>															
Interest income				0.0	0.0	0.0	0.1	0.2	0.3	0.3	0.4	0.4	0.5	0.5	0.5
Interest expense	(0.4)		0.0	0.0	0.5	0.6	2.2	2.2	2.2	2.2	2.2	2.2	1.6	1.6	1.6
Other	(8.6)	2.3				2.3									
<b>Total Other Income (Expense)</b>	(9.0)	2.3	0.0	0.0	0.6	2.9	2.3	2.4	2.4	2.5	2.5	2.6	2.1	2.1	2.1
<b>Income before Tax</b>	(31.2)	(6.7)	(11.8)	(12.1)	(11.7)	(42.3)	(50.0)	(55.1)	(56.6)	(36.6)	(146.7)	(303.0)	(432.2)	(615.9)	(779.2)
<b>Taxes</b>										12.4	49.9	103.0	146.9	209.4	264.9
<b>Net income (loss)</b>	(31.2)	(6.7)	(11.8)	(12.1)	(11.7)	(42.3)	(50.0)	(55.1)	(56.6)	(24.1)	(96.8)	(200.0)	(285.2)	(406.5)	(514.3)
EPS, Basic (GAAP)	(\$2.57)	(\$0.28)	(\$0.49)	(\$0.50)	(\$0.48)	(\$1.77)	(\$2.05)	(\$2.19)	(\$2.21)	\$0.92	\$3.63	\$7.36	\$9.95	\$12.31	\$15.27
EPS, Diluted (GAAP)	(\$1.51)	(\$0.23)	(\$0.41)	(\$0.36)	(\$0.34)	(\$1.33)	(\$1.45)	(\$1.56)	(\$1.58)	\$0.66	\$2.61	\$5.31	\$7.51	\$10.53	\$13.07
Shares outstanding, Basic	12.2	23.7	23.9	24.0	24.1	23.9	24.4	25.1	25.6	26.1	26.6	27.2	28.7	33.0	33.7
Shares outstanding, Diluted	20.7	28.4	28.6	33.9	34.0	31.2	34.5	35.3	35.9	36.5	37.1	37.7	38.0	38.6	39.3
EPS, Basic (Non-GAAP)	(\$2.46)	(\$0.20)	(\$0.39)	(\$0.36)	(\$0.32)	(\$1.27)	(\$1.19)	(\$1.50)	(\$1.53)	\$1.59	\$4.29	\$8.00	\$10.56	\$12.84	\$15.79
EPS, Diluted (Non-GAAP)	(\$1.44)	(\$0.17)	(\$0.33)	(\$0.25)	(\$0.23)	(\$0.97)	(\$0.84)	(\$1.06)	(\$1.09)	\$1.06	\$2.77	\$5.14	\$7.29	\$10.98	\$13.52
<b>Operating Ratios</b>	2013A	1Q:14A	2Q:14A	3Q:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
COGS									10.0%	10.0%	10.0%	10.0%	10.0%	10.0%	10.0%
Gross Margin	NA	NA	NA	NA	NA	NA	NA	NA	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%
R&D	NA	NA	NA	NA	NA	NA	NA	NA	532.7%	13.6%	5.7%	3.0%	2.1%	1.5%	1.2%
SG&A	NA	NA	NA	NA	NA	NA	NA	NA	456.6%	40.8%	20.4%	17.4%	17.5%	17.7%	17.8%
Operating Margin	NA	NA	NA	NA	NA	NA	NA	NA	-899.2%	37.0%	65.3%	71.0%	71.6%	72.0%	72.2%
Taxes	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%	34.0%
Net Margin	NA	NA	NA	NA	NA	NA	NA	NA	-862.1%	26.2%	43.9%	47.3%	47.5%	47.7%	47.8%

Source: Company reports and RBC Capital Markets estimates.

<b>Balance Sheet - Select Items</b>	2013A	1Q:14A	2Q:14A	3Q:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Cash and cash equivalents	69.6	35.8	27.9	143.2	133.8	133.8	89.3	41.7	(7.5)	11.6	84.9	241.7	492.7	846.4	1,314.1
Prepaid expenses and other current assets	0.6	0.7	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9	0.9
<b>Total current assets</b>	70.3	65.8	57.3	172.6	163.2	163.2	122.7	77.5	30.9	65.0	171.7	381.7	679.6	1,100.0	1,627.9
Property, plant and equipment, net	0.1	0.1	0.2	0.2	0.2	0.2	0.2	0.3	0.4	0.4	0.5	0.5	0.6	0.6	0.7
<b>Total assets</b>	70.5	66.0	57.7	173.0	163.7	163.7	123.2	78.1	31.5	65.7	172.5	382.5	680.4	1,101.0	1,628.9
<b>Current Liabilities</b>															
<b>Total current liabilities</b>	3.5	3.7	4.8	4.8	4.8	4.8	4.8	5.3	5.8	6.3	6.8	7.3	10.5	15.0	19.1
<b>Total liabilities</b>															
Share Capital	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Share Premium	162.0	164.0	166.4	166.4	166.4	166.4	166.4	166.4	166.4	166.4	166.4	166.4	166.4	166.4	166.4
Accumulated deficit	(95.1)	(101.7)	(113.6)	(123.2)	(132.6)	(132.6)	(173.0)	(218.6)	(265.7)	(232.1)	(125.8)	83.7	378.5	794.5	1,318.3
<b>Total stockholders' equity</b>	67.0	62.3	52.9	168.2	158.9	158.9	118.4	72.8	25.7	59.3	165.6	375.2	669.9	1,085.9	1,609.7
<b>Total liabilities and stockholders' equity</b>	70.5	66.0	57.7	173.0	163.7	163.7	123.2	78.1	31.5	65.7	172.5	382.5	680.4	1,101.0	1,628.9
<b>Cash Flow Statement - Select Items</b>	2013A	1Q:14A	2Q:14A	3Q:14E	4Q:14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Net Income (loss)	(31.2)	(6.7)	(11.8)	(12.1)	(11.7)	(42.3)	(50.0)	(55.1)	(56.6)	(24.1)	(96.8)	(200.0)	(285.2)	(406.5)	(514.3)
Depreciation and amortization	0.1	0.0	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Stock based compensation	2.9	1.9	2.4	2.4	2.4	9.1	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5	9.5
<b>Net cash provided (used) by operating activities</b>	(16.4)	(4.5)	(8.4)	(9.7)	(9.3)	(31.9)	(44.4)	(47.5)	(49.1)	19.2	73.5	156.9	251.1	353.9	467.8
Purchase of property and equipment and intangible assets	(0.1)	(0.0)	(0.0)	(0.0)	(0.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
<b>Net cash used in investing activities</b>	(0.1)	(29.4)	0.4	(0.0)	(0.0)	(29.0)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Proceeds from issuances	71.9														
<b>Net cash provided by (used in) financing activities</b>	83.2	0.1	0.0	125.0		125.1									
Decrease in cash and cash equivalents	66.7	(33.8)	(8.0)	115.3	(9.3)	64.2	(44.5)	(47.6)	(49.2)	19.1	73.3	156.7	251.0	353.7	467.7
<b>Cash and cash equivalents at the beginning of the year</b>	2.9	69.6	35.8	27.9	143.2	69.6	133.8	89.3	41.7	(7.5)	11.6	84.9	241.7	492.7	846.4
<b>Cash and cash equivalents at the end of the year</b>	69.6	35.8	27.9	143.2	133.8	133.8	89.3	41.7	(7.5)	11.6	84.9	241.7	492.7	846.4	1,314.1

Source: Company reports and RBC Capital Markets estimates.



## Required disclosures

### Conflicts disclosures

The analyst(s) responsible for preparing this research report received compensation that is based upon various factors, including total revenues of the member companies of RBC Capital Markets and its affiliates, a portion of which are or have been generated by investment banking activities of the member companies of RBC Capital Markets and its affiliates.

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#### Ratings

**Top Pick (TP):** Represents analyst's best idea in the sector; expected to provide significant absolute total return over 12 months with a favorable risk-reward ratio.

**Outperform (O):** Expected to materially outperform sector average over 12 months.

**Sector Perform (SP):** Returns expected to be in line with sector average over 12 months.

**Underperform (U):** Returns expected to be materially below sector average over 12 months.

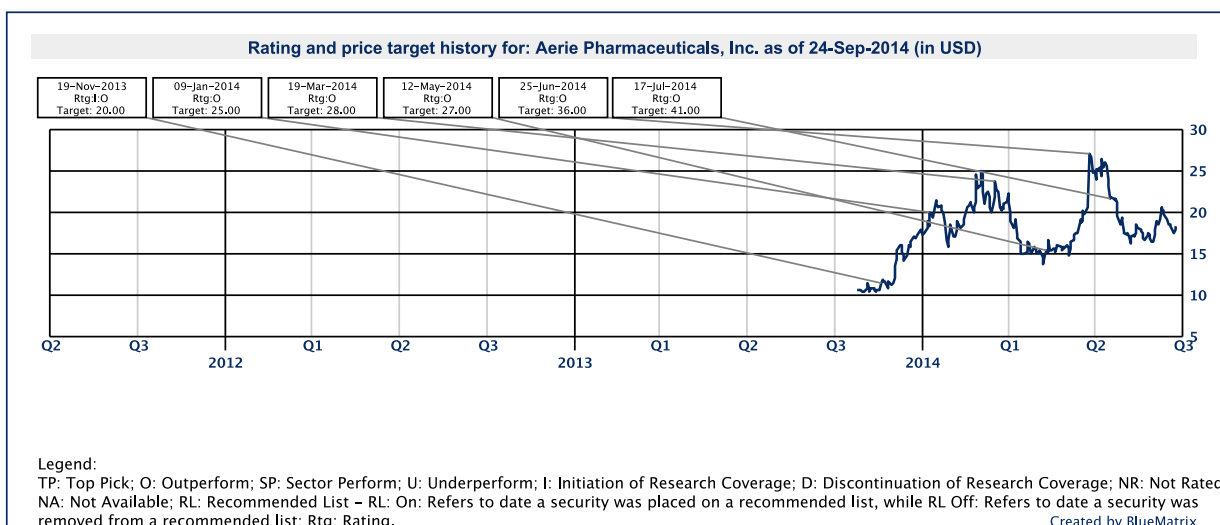
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Distribution of ratings				
RBC Capital Markets, Equity Research				
As of 30-Jun-2014				
Rating	Count	Percent	Investment Banking Serv./Past 12 Mos.	
			Count	Percent
BUY [Top Pick & Outperform]	845	53.24	299	35.38
HOLD [Sector Perform]	658	41.46	159	24.16
SELL [Underperform]	84	5.29	10	11.90



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