EQUITY RESEARCH

RBC Capital Markets

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Aerie Pharmaceuticals, Inc.

Several positives from NVS analyst day and AAO meeting and other tidbits

Our view: Positive – NVS underscored importance of combination glaucoma therapy and AAO meeting highlighted safety concerns with current second-line drugs; both favor AERI long-term

Key points:

AERI's two anti-glaucoma drugs could be ideally positioned to address the glaucoma market based on updates from the NVS investor day and the recently held American Academy of Ophthalmology (AAO) meeting. NVS highlighted the opportunity for combination drugs amongst current glaucoma drug trends. AERI's PG324 is a combination of AR-13324 and latanoprost and could be the ideal first-line drug. The recently held AAO meeting highlighted safety concerns with almost every second-line glaucoma drug, which would make AR-13324 an ideal drug choice for second-line therapy given its clean safety. Other tidbits show that patients continue to require anti-glaucoma drugs post surgical procedures and normal tension glaucoma patients benefit from glaucoma drugs as well. AR-13324 will enter Phase III trials and PG324 will enter and report data from a Phase IIb study in 2014, a potential key inflection point. We continue to see significant market opportunities from both product candidates.

Novartis commentary Friday (11/22) highlighted an opportunity for combination drugs in glaucoma. Novartis (NVS) expects growth for its combination glaucoma drug Simbrinza, a combination of brinzolamide + brimonidine. NVS also stated that one of the few segments that could grow in glaucoma therapy would be combination therapy. The attribute of Simbrinza that NVS highlighted was the fact that it excludes timolol, a beta blocker, which has systemic side effects. We note that AERI's drugs have clean safety and are not combined with beta blockers.

AAO overview of four major drug classes to treat glaucoma showed significant side effects with second-line drugs (*see following pages for a complete list of side effects and contraindications*). While all drug classes have side effects, second-line drugs are far worse than prostaglandins, the first-line drug of choice. Amongst second-line drugs, beta blockers have the worst safety profile, yet they still see the most widespread use after prostaglandins. Contraindications for both carbonic anhydrase inhibitors and beta blockers are serious. Compared to these drugs, we expect AERI's drugs, which inhibit rho kinase and norepinephrine transporter, to have a fairly clean safety profile.

News flow is near-term and rapid. Clinical results are expected in 2014 (Phase IIb for PG324), 2015 (Phase III for AR-13324), and 2016 (Phase III for PG324) and lead to value inflection opportunities as soon as mid-2014.

Outperform
Speculative Risk
NASDAQ: AERI; USD 11.64

Price Target USD 20.00

WHAT'S INSIDE

☐ Rating/Risk Change	☐ Price Target Change
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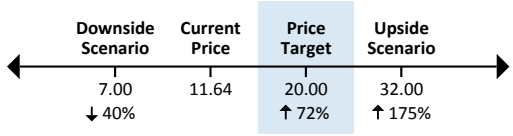
Scenario Analysis*



*Implied Total Returns

Key Statistics

Shares O/S (MM):	23.2	Market Cap (MM):	270
Dividend:	0.00	Yield:	0.0%

RBC Estimates

FY Dec	2013E	2014E	2015E
Revenue	0.0	0.0	0.0
EPS, Adj Diluted	(1.05)	(1.01)	(1.06)
P/AEPS	NM	NM	NM

Revenue	Q1	Q2	Q3	Q4
2013	0.0E	0.0E	0.0E	0.0E
2014	0.0E	0.0E	0.0E	0.0E
EPS, Adj Diluted				
2013	(0.41)E	(0.28)E	(0.22)E	(0.22)E
2014	(0.24)E	(0.25)E	(0.26)E	(0.26)E

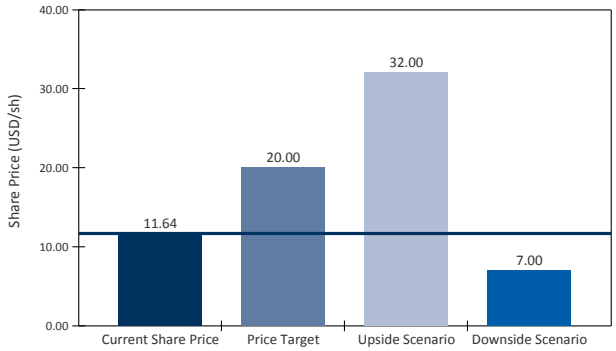
All values in USD unless otherwise noted.

Priced as of prior trading day's market close, EST (unless otherwise noted).

For Required Conflicts Disclosures, see Page 8

Target/Upside/Downside Scenarios

Exhibit 1: Aerie Pharmaceuticals, Inc.



Source: RBC Capital Markets estimates

Target price/ base case

We value AERI at $20 per share, which includes US and EU sales of AR-13324 and PG324. We assign a 60% probability of success and a value of ~$14 per share to the US and $6 per share to the EU opportunity. We assume a US launch in 2017 and an EU launch in 2018. We forecast peak PG324 sales of $700–800MM and AR-13324 sales of $200–300MM in the US and $500–600MM and $100–200MM in the 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 includes ~$23 per share in value for the US opportunity and ~$9 per share in value for the EU opportunity. We forecast peak PG324 sales of $1.2–1.3B in the US and $900M–$1B in the EU and AR-13324 sales of $200–300MM in the US and $200–300MM in the EU. We assign products in the pipeline a 60% probability of success, a discount rate of 15%, and a terminal growth rate of -50%.

Downside scenario

Our downside scenario assumes that PG324 will not be approved in the US or EU. We value the US opportunity for AR-13324 at $5 per share and the EU opportunity at $3 per share. We assume market share ramps up to roughly 15% of total second-line glaucoma prescriptions in the US and 10% in the EU. Under such a scenario, peak sales are forecast to be $400–500M in the US and $300–400MM in the EU. We assign AR-13324 a 60% 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, AR-13324 and PG324, use a new mechanism of action for the treatment of glaucoma, a blockbuster potential market. AR-13324 will enter Phase III trials based on positive Phase IIb data and PG324 a Phase IIb study based on promising preclinical data in 2014. 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 AR-13324 and PG324 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 IIb data for PG324 in 2014.** Important catalyst as it could show differentiation in efficacy vs. latanoprost, the current market leader.
- **Phase III data for AR-13324 in 2015.** Important catalyst as positive data could lead to an NDA and MAA filing.
- **Phase III data for PG324 in 2016.** Key catalyst as clean safety and efficacy beyond latanoprost could make PG324 the first-line drug of choice.
- **Potential partnership for AR-13324 and PG324.** 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 2018 in the EU** following regulatory filings in 2016.

Risks to Our Investment Thesis

- **Pivotal Phase III and earlier-stage studies could fail.** AR-13324 must show non-inferiority to a comparator over a longer period and PG324 must show a benefit in patients, which raises risk of failure.
- **PG324 Phase IIb study could fail.** Our assumption for success is based on pre-clinical data with PG324, and testing it in patients increases risk.
- **AERI could fail to find a partner** for AR-13324 and PG324 outside the US.
- **Sales ramp of AR-13324 and PG324 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.

Novartis commentary Friday (11/22) highlighted an opportunity for combination drugs in glaucoma

Novartis (NVS) expects growth for its combination glaucoma drug Simbrinza, a combination of brinzolamide + brimonidine (carbonic anhydrase inhibitor + alpha agonist). NVS also stated that one of the few segments that could grow in glaucoma therapy would be combination therapy. Its combination drugs include Azarga (brinzolamide + timolol, a carbonic anhydrase inhibitor + beta blocker) and Duotrav (travoprost + timolol), a prostaglandin + beta blocker. Azarga is dosed twice per day but Duotrav is dosed once per day. The attribute of Simbrinza that NVS highlighted was the fact that it excludes timolol, a beta blocker, which has systemic side effects. Both of the other NVS combination drugs include timolol.

AAO overview of four major drug classes to treat glaucoma showed significant side effects with second-line drugs

While all drug classes have side effects, second-line drugs are far worse than prostaglandins, the first-line drug of choice. Amongst second-line drugs, beta blockers have the worst safety profile, yet they still see the most widespread use after prostaglandins. Contraindications for both carbonic anhydrase inhibitors and beta blockers are serious. Compared to these drugs we expect AERI's drugs, which inhibit rho kinase and norepinephrine transporter, to have a fairly clean safety profile.

Alpha-adrenergic agonists (sympathomimetics / parasympathomimetics)

Drugs such as Iopidine (apraclonidine), Alphagan (brimonidine).

- **Adverse events:** Eye irritation, hyperemia, allergy, lid twitch, headaches, etc.
- **Serious adverse events:** Blood-aqueous barrier decrease, cataract, retinal detachment, conjunctival scars, blurred vision, headaches, etc.
- **Potential systemic side effects:** Nausea, vomiting, pulmonary edema, hypertension, cardiac arrhythmias, dizziness, etc.
- **Contraindications:** Preoperative use, cataracts, retinal detachment risks, hypertension, diabetes, narrow angle glaucoma.

Carbonic anhydrase inhibitors

Drugs such as Trusopt (dorzolamide), Azopt (brinzolamide). These are the only drug class that can be administered systemically. However, systemic administration leads to even greater side effects than topical administration in patients.

- **Adverse events:** Myopia.
- **Serious adverse events:** Stevens-Johnson syndrome.
- **Potential systemic side effects:** Paresthesias, urinary frequency, metallic taste, cramps, diarrhea, constipation, fatigue, depression, decreased libido, exfoliative dermatitis, Stevens-Johnson syndrome, and hypokalemia, among others.
- **Contraindications:** Kidney stones, skin problems, sulfonamide reactions, kidney or liver disease.

Beta-blockers (beta-adrenergic receptor blockers)

Drugs such as timolol, etc., have the longest lists of side effects associated with them and also carry significant contraindications.

- **Adverse events:** Allergy, irritation, headache, visual disturbances, reduced tear production, etc.
- **Serious adverse events:** Macular edema, retinal detachment, uveitis, cataract, etc.

- **Potential systemic side effects:** Bradycardia, palpitations, hypotension, syncope, congestive heart failure, bronchospasm, dyspnea, respiratory failure, paresthesias, confusion, lightheadedness, depression, insomnia, memory loss, nausea, diarrhea, rash, nail pigment changes, impotence, hyperglycemia, and many more.
- **Contraindications:** Asthma, cardiovascular problems, interaction with MAO inhibitors.

Prostaglandin analogs

Drugs include Xalatan (latanoprost), Travatan (travoprost), Lumigan (bimatoprost), and Rescula (unoprostone isopropyl). Most prostaglandins are administered once per day except for Rescula, which must be given twice per day.

- **Adverse events:** Increased brown pigment in the iris, conjunctival hyperemia, eyelash growth.
- **Serious adverse events:** Cystoid macular edema, uveitis.
- **Potential systemic side effects:** N/A.
- **Contraindications:** Cystoid macular edema, uveitis.

Patients with tube or trabeculectomy stay on medication

A session on glaucoma management mentioned that on average patients who have undergone a tube shunt surgery procedure stay on 1.3 and those after a trabeculectomy stay on 1.0 medications for the treatment of glaucoma. For most surgical procedures, treatment is considered a failure if intraocular pressure (IOP) >21 mmHg or not reduced by 20% from baseline or IOP <=5 mmHg. Some on the Street worried about competition from surgical procedures, but data presented at the AAO meeting gives us confidence that both AERI products could be useful even for patients who undergo surgeries.

Normal tension glaucoma patients require anti-glaucoma drugs as well

Normal intraocular pressures is defined as 15.5 mmHg (mean) and two standard deviations above it means 20.5 mmHg. Alphagan (brimonidine) has demonstrated better outcomes in patients with NTG than timolol with less glaucoma progression. IOP reduction is still the only proven therapy for normal tension glaucoma with the best evidence from a randomized controlled trial coming with an alpha agonist. We believe the opportunity exists for AR-13324 and PG324 to demonstrate efficacy in patients with normal tension glaucoma as well.

News flow is near-term and rapid

AR-13324 Phase III studies and a PG324 Phase IIb study will begin in 2014. Clinical results are expected in 2014 (Phase IIb for PG324), 2015 (Phase III for AR-13324), and 2016 (Phase III for PG324) and could help determine the ultimate market potential of AERI's drugs and lead to value inflection opportunities as soon as mid-2014 as we believe PG324 Phase IIb is as important as Phase III AR-13324 results.

News Flow

Timing	Expected News Flow	Program
Early 2014	Initiate Phase IIb studies in glaucoma	PG324
1Q:14	3-month data from 6- and 9 -month tox studies	AR-13324
Mid-2014	Initiate Phase III trials in glaucoma	AR-13324
Mid-2014	Phase IIb results	PG324
2014 / 2015	Final 6- and 9-month data from 2 tox studies	AR-13324
2014 / 2015	Potential ex-US partnership(s)	
Mid-2015	Efficacy results from Phase III studies	AR-13324
1H / Mid-2015	Initiate Phase III trials in glaucoma	PG324
2H:15 / Early 2016	Phase III results in glaucoma	AR-13324
2015 / 2016	Initiate Phase I trials	AR-13533
Mid-2016	File NDA	AR-13324
1H / Mid-2016	Efficacy results from Phase III studies	PG324
2H:16 / Early 2017	Phase III results in glaucoma	PG324
1H / mid-2017	Expect approval and launch	AR-13324
Mid-2017	File NDA	PG324
Mid-2018	Expect approval and launch	PG324

Source: Company reports.

Pipeline

Product	Mechanism	Stage	Indication	Partner
AR-13324	Dual-action ROCK / NET inhibitor	Phase III planned	Glaucoma	
PG324	Triple-action ROCK / NET inhibitor and latanoprost, a PGA	Phase IIb planned	Glaucoma	
AR-13533	Dual-action ROCK / NET inhibitor	Pre-clinical	Glaucoma	

Source: Company reports.

Valuation

We value AERI at $20 per share, which includes US and EU sales of AR-13324 and PG324. We assign a probability of success of 65% to both products and a value of ~$14 per share to the US and $6 per share to the EU opportunity. We assume a US launch in 2017 and an EU launch in 2018. Currently, we assume that AERI will sell AR-13324 and PG324 in the US and a partner will commercialize these compounds outside the US. We forecast peak PG324 sales of $700–800MM in the US and $500–600MM in the EU and AR-13324 sales of $200–300MM in the US and $100–200MM in the US. We currently assign no additional value to the earlier-stage pipeline. Finally, we assume product sales extend through 2030 and include a terminal value based on a discount rate of 15% and a terminal growth rate of -50%.

Price target impediments

Our price target is dependent solely on the clinical, regulatory and commercial success of AR-13324 and PG324. A Phase IIb study for PG324 and a Phase III study for AR-13324 are expected in 2014 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 AR-13324 and PG324, 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 markets. 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. AR-13324 could enter Phase III trials in 2014 and PG324 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)	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
REVENUES											
AR-13324					6.5	69.1	147.3	235.5	209.2	178.4	142.6
PG324						7.5	31.8	101.8	180.8	308.4	410.9
Product Sales					6.5	76.5	179.1	337.2	390.0	486.8	553.5
Royalties						9.3	22.9	41.1	45.4	54.0	58.6
Other											
Total Revenues					6.5	85.8	202.0	378.4	435.3	540.8	612.1
EXPENSES											
COGS					0.6	7.7	17.9	33.7	39.0	48.7	55.4
R&D	13.0	16.5	20.0	22.5	20.0	10.0	5.0	5.0	5.0	5.0	5.0
SG&A	7.0	7.5	8.5	15.0	30.0	37.5	45.0	67.4	78.0	97.4	110.7
Other											
Total Expenses	19.9	24.0	28.5	37.5	50.6	55.2	67.9	106.2	122.0	151.0	171.1
Operating Income (Expense)	(19.9)	(24.0)	(28.5)	(37.5)	(44.2)	30.6	134.1	272.2	313.3	389.7	441.0
OTHER											
Interest income	0.2	0.4	0.4	0.5	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Interest expense	(0.7)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)	(0.2)
Other											
Total Other Income (Expense)	(0.5)	0.2	0.2	0.3	0.3	0.3	0.3	0.3	0.3	0.3	0.3
Income before Tax	(20.4)	(23.8)	(28.3)	(37.2)	(43.9)	30.9	134.4	272.5	313.6	390.0	441.3
Taxes						10.5	45.7	92.6	106.6	132.6	150.1
Net income (loss)	(20.4)	(23.8)	(28.3)	(37.2)	(43.9)	20.4	88.7	179.8	207.0	257.4	291.3
EPS, Basic (GAAP)	($1.05)	($1.01)	($1.06)	($1.24)	($1.44)	$0.66	$2.80	$5.56	$6.27	$7.65	$8.48
EPS, Diluted (GAAP)	($0.73)	($0.74)	($0.81)	($0.97)	($1.13)	$0.52	$2.20	$4.40	$4.99	$6.11	$6.80
Shares outstanding, Basic	19.4	23.6	26.6	29.9	30.5	31.1	31.7	32.4	33.0	33.7	34.3
Shares outstanding, Diluted	27.9	32.1	35.1	38.4	39.0	39.6	40.2	40.9	41.5	42.2	42.8
Operating Ratios	2013E	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	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%	90.0%
R&D	NA	NA	NA	NA	308.7%	11.7%	2.5%	1.3%	1.1%	0.9%	0.8%
SG&A	NA	NA	NA	NA	463.0%	43.7%	22.3%	17.8%	17.9%	18.0%	18.1%
Operating Margin	NA	NA	NA	NA	-681.7%	35.7%	66.4%	71.9%	72.0%	72.1%	72.1%
Taxes	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	-677.1%	23.8%	43.9%	47.5%	47.6%	47.6%	47.6%

Source: Company reports and RBC Capital Markets estimates.

Balance Sheet - Select Items	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Cash and cash equivalents	61.3	39.2	102.5	65.0	20.8	29.1	88.6	222.7	416.5	648.1	922.3
Prepaid expenses and other current assets	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Total current assets	62.5	40.3	107.7	72.6	30.9	53.5	144.3	326.3	535.8	796.3	1,090.2
Property, plant and equipment, net	0.1	0.0	(0.0)	(0.1)	(0.1)	(0.2)	(0.2)	(0.3)	(0.3)	(0.4)	(0.4)
Total assets	62.6	40.4	107.7	72.6	30.8	53.3	144.1	326.1	535.5	795.9	1,089.8
Current Liabilities											
Total current liabilities	11.8	11.8	11.8	12.3	12.8	13.3	13.8	14.3	15.1	16.5	17.5
Total liabilities	4.6	4.6	4.6	4.6	4.6	4.6	4.6	4.6	4.6	4.6	4.6
Share Capital	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Share Premium	68.5	68.5	162.5	162.5	162.5	162.5	162.5	162.5	162.5	162.5	162.5
Accumulated deficit	(83.5)	(105.7)	(132.4)	(168.0)	(210.3)	(188.2)	(98.0)	83.5	292.1	551.1	844.0
Total stockholders' equity	46.2	24.0	91.3	55.7	13.4	35.5	125.7	307.2	515.8	774.8	1,067.7
Total liabilities and stockholders Equity	62.6	40.4	107.7	72.6	30.9	53.4	144.2	326.1	535.5	795.9	1,089.8
Cash Flow Statement - Select Items	2013E	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E
Net Income (loss)	(20.4)	(23.8)	(28.3)	(37.2)	(43.9)	20.4	88.7	179.8	207.0	257.4	291.3
Depreciation and amortization	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Stock based compensation	1.2	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6	1.6
Net cash provided (used) by operating activities	(17.0)	(22.1)	(30.6)	(37.5)	(44.1)	8.4	59.6	134.2	193.8	231.6	274.3
Purchase of property and equipment and intangible assets	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Net cash used in investing activities	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)	(0.1)
Proceeds from issuances	68.4		94.0								
Net cash provided by (used in) financing activities	75.4		94.0								
Decrease in cash and cash equivalents	58.4	(22.1)	63.4	(37.5)	(44.2)	8.3	59.5	134.1	193.7	231.6	274.2
Cash and cash equivalents at the beginning of the year	2.9	61.3	39.2	102.5	65.0	20.8	29.1	88.6	222.7	416.5	648.1
Cash and cash equivalents at the end of the year	61.3	39.2	102.5	65.0	20.8	29.1	88.6	222.7	416.5	648.1	922.3

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.

Risk Rating

As of March 31, 2013, RBC Capital Markets suspends its Average and Above Average risk ratings. The **Speculative** risk rating reflects a security's lower level of financial or operating predictability, illiquid share trading volumes, high balance sheet leverage, or limited operating history that result in a higher expectation of financial and/or stock price volatility.

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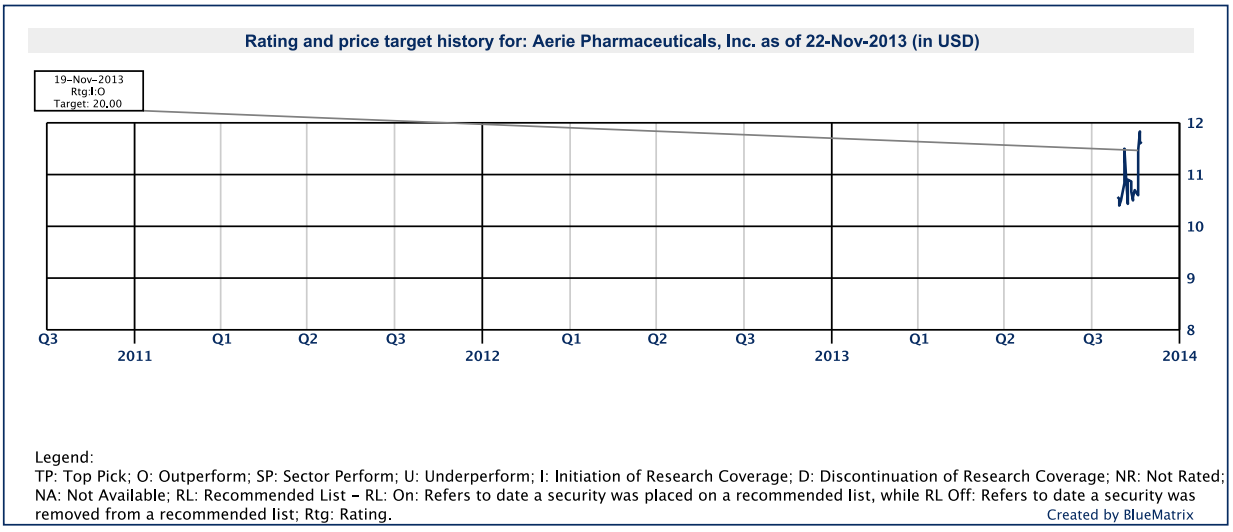
Distribution of ratings
RBC Capital Markets, Equity Research
As of 30-Sep-2013

			Investment Banking Serv./Past 12 Mos.	
Rating	Count	Percent	Count	Percent
BUY [Top Pick & Outperform]	769	51.00	271	35.24
HOLD [Sector Perform]	656	43.50	179	27.29
SELL [Underperform]	83	5.50	13	15.66



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