Avalanche Biotechnologies (AAVL)

Q1 EPS Takeaways; All Eyes on AVA-101 Phase IIa Data in Mid-15

Buy

Price Target: $60.00
Prior: $60.00

Price (May 12, 2015)	$33.88
52-Wk Range	$60.08-$22.60
Market Cap ($M)	$854
ADTV	311,000
Shares Out (M)	25.2
Short Interest Ratio/% Of Float	10.4%
TR to Target	77.1%

Cash Per Share	$8.02
Cash And Equivalents ($M)	$290.1

	2014A	2015E		2016E	
		Curr.	Prior	Curr.	Prior
EPS Adjusted					
1Q	($0.45)	($0.38)A	($0.43)	--	
2Q	($2.27)	($0.50)	($0.54)	--	
3Q	($0.50)	($0.62)	($0.66)	--	
4Q	($0.46)	($0.71)	($0.72)	--	
FY	($2.46)	($2.21)	($2.36)	($3.10)	($3.11)
P/E	NM	NM		NM	
Consensus EPS Adjusted					
FY	($2.61)	($1.82)	($1.68)	($2.28)	($1.80)
Revenue ($M)					
FY	$1	$1	$0	$0	$0
P/Sales	853.8x	853.8x		--	
Consensus Rev					
FY	$1	$0	$0	$0	$0

FYE Dec
Quarterly values may not add to the annual value due to rounding.

What's Incremental
AAVL reported Q1 revenue of $0.2M, related to amortization of an upfront payment from collaborator REGN. Q1 EPS of $(0.38) was in line with consensus at $(0.40) and higher than STRH of $(0.43). The company ended Q1/15 with $290M in cash, which we expect will be sufficient to fund operations through 2017. Timelines for lead gene therapy product AVA-101 in wet AMD are intact, and we look towards a number of presentations at the ASGCT conference (previewed here). We recommend investors own AAVL into the mid-15 AVA-101 data readout.

The key catalyst for AAVL is AVA-101 Phase IIa data readout in mid-15, 36-month Phase I data to support durability. The key investor question relates to read through of impressive Phase I results for the gene therapy AVA-101 in wet AMD, to the ongoing Phase IIa. However, baseline characteristics of Phase IIa study patients are suggestive of milder disease (and more representative of the broad wet AMD population), compared to the Phase I trial. A summary of patient demographics for this study was presented by AAVL at the R&D Day in March, and we look towards a more detailed poster presentation at the American Society of Gene and Cell Therapy (ASGCT), on May 14th. Thus, it is likely that AVA-101 activity in the Phase IIa study results in a more modest clinical benefit compared to the Phase I trial. Another investor question relates to persistence of AVA-101 activity (post a New England Journal of Medicine article for a different gene therapy showed declining effect in out years, in a rare genetic eye disorder - discussed here). AAVL announced that 36-month follow-up data from the Phase I trial are expected in mid-15 (topline) with a presentation at a medical meeting in H2/15. We look towards continued benefit with AVA-101, with respect to fewer rescue Lucentis injections vs. control within a one year period and maintained vision acuity.

Pipeline updates reflect intact timelines for lead program AVA-101. 12-month results from the Phase IIa study of AVA-101 in wet AMD are expected in mid-15. A U.S. Phase IIb study of AVA-101 is slated to begin in H2/15, to take place mainly in the U.S. We look towards 1) presentation of baseline Phase IIa characteristics at the ASGCT conference, 2) Phase IIa AVA-101 results in wet AMD in mid-15, 3) potential REGN opt-in for AVA-101, 4) 36-month follow-up data from the Phase I study in mid-15, 5) launch of a Phase IIb U.S. study of AVA-101 in wet AMD.

Changes to model post Q1 EPS. AAVL reported $5.6M in R&D expense, lower than our $7.55M estimate. Q1 SG&A expense was $4.1M, higher than STRH at $3.4M. The company ended the quarter with $290.1M in cash, expected to support operations into 2017. Given the current R&D spend trajectory and the company's expected cash runway guidance, we are adjusting

Salveen Richter, CFA
212-319-3728
salveen.richter@suntrust.com

Raluca Pancratov, Ph.D.
212-303-4178
raluca.pancratov@suntrust.com

SEE PAGE 6 FOR REQUIRED DISCLOSURE INFORMATION

our FY15+ OpEx estimates. Our FY15 R&D estimate is adjusted to $35.6M from $42.8M previously, while our FY15 SG&A estimate is increased to $20.9M from $16.9M previously. Our FY15 EPS estimate is now $(2.21) versus $(2.36) previously.

Figure 1: Q1/15 Variance Table

Avalanche Biotechnologies

(NASDAQ: AAVL)

Consolidated Income Statement

($thousands, except per share data)	Mar Q1 2015A	Mar Q1 2015E	Variance A-E	Variance %	Y/Y %	Q/Q %
Revenue						
AVA-101	-	-	-			
AVA-201	-	-	-			
AVA-311	-	-	-			
Other	-	-	-			
Total product revenue	-	-	-			
Collaboration and license revenue	203	203	-	0%	577%	0%
Total Revenue	203	203	-	0%	577%	0%
COGS	-	-	-			
Gross profit	203	**203**	-	0%	577%	0%
Operating expense	-	-	-			
R&D (GAAP)	5,621	**7,555**	(1,934)	-34%	518%	-22%
SG&A (GAAP)	4,143	**3,401**	742	18%	471%	23%
Stock-based compensation	-	-	-			
Total operating expense	9,764	**10,956**	(1,192)	-12%	497%	-8%
Operating income (loss)	**(9,561)**	**(10,753)**	**1,192**	**-12%**	**495%**	**-8%**
Total Other Income	**52**	**16**	**36**	68%	-191%	333%
Income before income taxes	**$ (9,509)**	**$ (10,737)**	**1,228**	**-13%**	**472%**	**-8%**
Provision for income taxes	-	-	-			
Net gain (loss)	(9,509)	(10,737)	1,228	-13%	472%	-8%
Net gain (loss) applicable to common shareholders	(9,509)	(10,737)	1,228	-13%	472%	-8%
GAAP EPS (diluted)	(0.38)	(0.43)	0.05	-13%	-16%	-17%
Weighted shares outstanding	-	-	-			
basic and diluted (k)	24,887	24,779	108	0.44%	578%	10%

Source: STRH analysis and Company reports

Figure 2: Upcoming Expected Milestones

Product	Timing	Indication	Event
AVA-101	Spring 2015	Wet age-related macular degeneration (wet AMD)	Presentation of baseline Phase IIa patient characteristics
AVA-101	**Mid-2015**	**Wet age-related macular degeneration**	**Readout of a Phase IIa study**
AVA-101	Mid-2015	Wet age-related macular degeneration	Potential Regeneron opt-in
AVA-101	H2 2015	Wet age-related macular degeneration	U.S. IND Filing
AVA-101	**Mid-2015**	**Wet age-related macular degeneration**	**36-month data from the Phase I study (topline)**
AVA-101	**H2 2015**	**Wet age-related macular degeneration**	**Conference presentation of 36-month Phase I data**
AVA-201	2015	Prevention of wet AMD	Completion of preclinical work for IND filing
AVA-322/AVA-323	H2 2016	Color Blindness	U.S. IND Filing

Source: STRH analysis and Company reports

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Avalanche Biotechnologies

(NASDAQ: AAVL)

Salveen Richter, CFA
(212) 319-3728
salveen.richter@suntrust.com

Consolidated Income Statement

($thousands, except per share data)	FY 2014A	Mar Q1 2015A	Jun Q2 2015E	Sep Q3 2015E	Dec Q4 2015E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
Revenue											
AVA-101	$ -	-	-	-	-	$ -	$ -	$ -	$ -	$ -	$ 128,387
Total product revenue						$ -	$ -	$ -	$ -	$ -	$ 128,387
Collaboration and license revenue	**572**	203	203	203	203	**812**	**812**	**812**	**812**	**812**	**812**
Total Revenue	**$ 572**	**$ 203**	**$ 203**	**$ 203**	**$ 203**	**$ 812**	**$ 812**	**$ 812**	**$ 812**	**$ 812**	**$ 129,199**
COGS	-	-	-	-	-	-	-	-	-	-	6,419
Gross profit	572	203	203	203	203	812	812	812	812	812	122,779
Operating expense											
R&D (GAAP)	16,976	5,621	7,978	10,121	11,901	35,621	72,221	98,041	118,334	132,711	143,560
SG&A (GAAP)	7,998	4,143	4,744	5,711	6,302	20,900	25,556	34,210	42,502	65,114	87,001
Stock-based compensation	8,564	-	-	-	-	-	-	-	-	-	-
Total operating expense	24,974	9,764	12,722	15,832	18,203	56,521	97,777	132,251	160,836	197,825	230,561
Operating income (loss)	**(24,402)**	**(9,561)**	**(12,519)**	**(15,629)**	**(18,000)**	**(55,709)**	**(96,965)**	**(131,439)**	**(160,024)**	**(197,013)**	**(107,782)**
Interest Income (expense), net	(6)	52	65	62	58	238	127	173	134	130	122
Other income (expense), net	(70)	-	-	-	-	-	-	-	-	-	-
Change in fair value of warrant liabilities	(722)										
Total Other Income	(1,002)	52	65	62	58	238	127	173	134	130	122
Deemed dividend	(3,230)										
Income before income taxes	(25,404)	(9,509)	(12,454)	(15,567)	(17,942)	(55,471)	(96,838)	(131,266)	(159,890)	(196,883)	(107,659)
Provision for income taxes	-	-	-	-	-	-	-	-	-	-	-
Net gain (loss)	**(28,634)**	**(9,509)**	**(12,454)**	**(15,567)**	**(17,942)**	**(55,471)**	**(96,838)**	**(131,266)**	**(159,890)**	**(196,883)**	**(107,659)**
FX translation adjustment											
Net gain (loss) applicable to common shareholders	**$ (28,634)**	**$ (9,509)**	**$ (12,454)**	**$ (15,567)**	**$ (17,942)**	**$ (55,471)**	**$ (96,838)**	**$ (131,266)**	**$ (159,890)**	**$ (196,883)**	**$ (107,659)**
GAAP EPS (diluted)	**$ (2.46)**	**$ (0.38)**	**$ (0.50)**	**$ (0.62)**	**$ (0.71)**	**$ (2.21)**	**$ (3.10)**	**$ (4.16)**	**$ (4.83)**	**$ (5.28)**	**$ (2.75)**
Weighted shares outstanding basic and diluted (k)	11,651	24,887	25,011	25,136	25,262	25,074	31,229	31,541	33,118	37,274	39,138
Margin Analysis:											
Cost of product sales	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	5%	5%
Product gross margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	95%	95%
R&D (GAAP)	2968%	2769%	3930%	4986%	5863%	4387%	8894%	12074%	14573%	16344%	111%
SG&A (GAAP)	1398%	2041%	2337%	2813%	3104%	2574%	3147%	4213%	5234%	8019%	67%
Stock-based compensation expense	1497%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Total operating expense	4366%	4810%	6267%	7799%	8967%	6961%	12042%	16287%	19807%	24363%	178%
Operating margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	-19707%	-24263%	-83%
Income tax provision	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Net margin (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	-19691%	-24247%	-83%
Y/Y change:											
Total revenue	119%	677%	150%	100%	100%	142%	100%	100%	100%	100%	15911%
AVA-101 revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
R&D (GAAP)	689%	518%	158%	76%	65%	110%	103%	36%	21%	12%	8%
SG&A (GAAP)	349%	471%	218%	138%	86%	161%	22%	34%	24%	53%	34%
Stock-based compensation expense	N/A	0%	0%	0%	0%	0%	N/A	N/A	N/A	N/A	N/A
Total operating expense	535%	497%	177%	94%	72%	126%	73%	35%	22%	23%	17%
Operating income	606%	495%	181%	97%	73%	128%	74%	36%	22%	23%	-45%
Net income (GAAP)	440%	472%	50%	88%	73%	94%	75%	36%	22%	23%	-45%
GAAP EPS (diluted)	70%	-16%	-78%	23%	54%	10%	-40%	-34%	-16%	-9%	48%
Shares outstanding - GAAP	217%	578%	581%	53%	12%	115%	25%	1%	5%	13%	5%

Source: STRH Research, Company Reports

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Avalanche Biotechnologies

(NASDAQ: AAVL)

Consolidated Income Statement

($thousands, except per share data)	FY15E		FY16E		FY17E		FY18E		FY19E		FY20E	
	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior
Revenue												
AVA-101	-	-	-	-	-	-	-	-	-	-	128,387	128,387
AVA-201	-	-	-	-	-	-	-	-	-	-	-	-
AVA-311	-	-	-	-	-	-	-	-	-	-	-	-
Other	-	-	-	-	-	-	-	-	-	-	-	-
	-	-	-	-	-	-	-	-	-	-	-	-
Total product revenue	-	-	-	-	-	-	-	-	-	-	128,387	128,387
	-	-	-	-	-	-	-	-	-	-	-	-
Collaboration and license revenue	812	812	812	812	812	812	812	812	812	812	812	812
	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenue	812	812	812	812	812	812	812	812	812	812	129,199	129,199
COGS	-	-	-	-	-	-	-	-	-	-	6,419	6,419
Gross profit	812	812	812	812	812	812	812	812	812	812	122,779	122,779
	-	-	-	-	-	-	-	-	-	-	-	-
Operating expense	-	-	-	-	-	-	-	-	-	-	-	-
R&D (GAAP)	35,621	42,855	72,221	72,221	98,041	98,041	118,334	118,334	132,711	132,711	143,560	143,560
SG&A (GAAP)	20,900	16,958	25,556	25,556	34,210	34,210	42,502	42,502	65,114	65,114	87,001	87,001
Stock-based compensation	-	-	-	-	-	-	-	-	-	-	-	-
Total operating expense	56,521	59,813	97,777	97,777	132,251	132,251	160,836	160,836	197,825	197,825	230,561	230,561
	-	-	-	-	-	-	-	-	-	-	-	-
Operating income (loss)	$ (55,709.00)	$ (59,001.00)	$ (96,965.00)	$ (96,965.00)	$ (131,439.00)	$ (131,439.00)	$ (160,024.00)	$ (160,024.00)	$ (197,013.00)	$ (197,013.00)	$ (107,781.55)	$ (107,781.55)
	-	-	-	-	-	-	-	-	-	-	-	-
Total Other Income	**238**	**74**	**127**	**122**	**173**	**169**	**134**	**129**	**130**	**124**	**122**	**116**
Deemed dividend	-	-	-	-	-	-	-	-	-	-	-	-
Income before income taxes	**$ (55,471)**	**$ (58,927)**	**$ (96,838)**	**$ (96,843)**	**$ (131,266)**	**$ (131,270)**	**$ (159,890)**	**$ (159,895)**	**$ (196,883)**	**$ (196,889)**	**$ (107,659)**	**$ (107,666)**
Provision for income taxes	-	-	-	-	-	-	-	-	-	-	-	-
Net gain (loss)	**(55,471)**	**(58,927)**	**(96,838)**	**(96,843)**	**(131,266)**	**(131,270)**	**(159,890)**	**(159,895)**	**(196,883)**	**(196,889)**	**(107,659)**	**(107,666)**
FX translation adjustment	-	-	-	-	-	-	-	-	-	-	-	-
Net gain (loss) applicable to common shareholders	(55,471)	(58,927)	(96,838)	(96,843)	(131,266)	(131,270)	(159,890)	(159,895)	(196,883)	(196,889)	(107,659)	(107,666)
GAAP EPS (diluted)	**(2.21)**	**(2.36)**	**(3.10)**	**(3.11)**	**(4.16)**	**(4.18)**	**(4.83)**	**(4.85)**	**(5.28)**	**(5.30)**	**(2.75)**	**(2.76)**
Weighted shares outstanding basic and diluted (k)	25,074	24,965	31,229	31,118	31,541	31,429	33,118	33,000	37,274	37,151	39,138	39,008
Cash, cash equivalents and marketable securities	-	-	547,012.0	533,938.0	415,573.0	402,499.0	255,549.0	242,475.0	308,536.0	295,462.0	200,754.4	187,680.4
	-	-	-	-	-	-	-	-	-	-	-	-

Source: STRH Research, Company Reports

Company Description

Avalanche Biotechnologies, Inc. is a clinical-stage biotechnology company that develops novel gene therapies to treat patients with sight-threatening ophthalmic diseases. Its products are used for the treatment of wet age-related macular degeneration and Juvenile X-linked Retinoschisis by inducing a sustained expression of a therapeutic protein with a one-time administration in the eye. The company was founded by Mark S. Blumenkranz, Thomas W. Chalberg and Steven D. Schwartz on July 17, 2006 and is headquartered in Menlo Park, CA.

Investment Thesis

Avalanche is one of the slew of new entrants in the biotech space, focused on gene therapy. Broad investor interest in the renaissance of gene therapy is evidenced by the strong performance of most of these stocks over their S1 price. Furthermore, AAVL shares are currently down off its highs at the end of December, providing an entry point ahead of readout of the Phase IIa study of lead product AVA-101 for wet age-related macular degeneration (AMD) in mid-2015. This product consists of an adeno-associated vector-based gene therapy, with the potential to disrupt and expand the $6B+ anti-VEGF market. Clinical results generated to date are suggestive of activity in a small number of patients with advanced disease. A randomized Phase IIa single center study is ongoing in Australia, with results expected, as noted, mid-2015. Given AVA-101's mechanism of action similar to anti-vascular endothelial growth factor (VEGF) biologics Lucentis and Eylea, the product could also have utility beyond wet AMD, in diseases such as retinal vein occlusion or diabetic macular edema (where Lucentis and Eylea are the standard of care). A follow-on preclinical gene therapy product AVA-201 is expected to undergo IND-enabling studies in 2015 for the prevention of high risk wet AMD. Avalanche is collaborating with Regeneron for the development of novel gene therapies for eye diseases, with the first product (preclinical stages) AVA-311 to address the orphan disease X-linked retinoschisis (XLRS). Notably, Regeneron also retains a time-limited right to first negotiation of rights to AVA-101.

Valuation and Risks

Valuation

We arrive at our price target of $60 by means of a sum-of-the-parts discounted cash flow analysis, which ascribes $46.24/share to AVA-101 U.S. sales, $6.11 to AVA-101 E.U. sales, and $8.04/share to cash. We assign AVA-101 in a probability of success of 55% in the U.S. and 25% in the E.U. We assume a discount rate of 12% and a 1% terminal growth rate. We do not model for any additional indications for AVA-101 beyond wet AMD. We do not include any value for AVA-201, AVA-311, or any other follow on products in our valuation.

Investment risks

The primary investment risks for Avalanche include the following:

• **Clinical and safety risk**: Phase I results presented to date showcased some intriguing signs of activity for Avalanche's AVA-101. The limitations of these data, however, include the small number of patients, a single center whereby doctors were well familiar with subretinal injection, and participants with advanced wet AMD who experienced tremendous increases in best corrected visual acuity. There remains the risk that Phase IIa and Phase IIb data do not recapitulate earlier findings due to differences in patient baseline characteristics, variability in time of assessment and determination of whether an anti-VEGF injection is needed, variability in efficacy measurements. There also remains a risk (albeit minimal) that in vivo dosing of AVA-101 could lead to an exaggerated immune reaction, resulting in loss of anti-VEGF molecule expression of significant loss of eye tissue.
• **Regulatory risk:** No gene therapy product has been approved in the U.S. to date, and in spite of the FDA's guidance there remain questions about the appropriate study design for pivotal gene therapy trials, especially for orphan diseases. The agency may require additional information on manufacturing methodology, as well as facilities where all the moving parts of a complex therapy are generated.
• **Commercial risk:** Given the novelty of gene therapy, there remains a risk that physicians are reluctant to prescribe AVA-101 to their patients. We note the risk of AVA-101 not reaching our sales estimates due to potential pricing and reimbursement issues, lower than expected penetration, or lack of ability to effectively target the broad wet AMD market.

• **Competitive Risk:** AVA-101 is entering the established wet AMD market, where two branded products (RHHBY's Lucentis and REGN's Eylea) and off-label Avastin are competing for share of the prevalent patient pool. Furthermore, AVA-101 competes with products such as Ophthotech's Fovista and Allergan's DARPins, which offer alternatives to the current anti-VEGF standard of care. Beyond monthly or every other month injections, AVA-101 is also competing with other gene therapies, including Sanofi/Genzyme's rAAV2-sFLT01, which has also completed Phase I testing. There is a risk that AVA-101 would not capture significant share of the wet AMD market, or of the retinal vein occlusion or diabetic macular edema markets.
• **Financial and partnership risk:** Avalanche does not currently recognize any revenue related to product sales. Given the expenses associated with clinical drug development, we forecast that the company could issue additional equity to finance its activities. There remains a risk that the company's cash reserves may be significantly depleted while attempting to fulfill collaborative obligations for partner Regeneron. There is a risk that no appropriate candidates emerge from the collaboration with Regeneron, thereby jeopardizing the non-dilutive cash inflow associated with this partnership (we do not model for any revenue associated with the partnership apart from the $6.5M upfront payment).

Analyst Certification

I, Salveen Richter , hereby certify that the views expressed in this research report accurately reflect my personal views about the subject company(ies) and its (their) securities. I also certify that I have not been, am not, and will not be receiving direct or indirect compensation in exchange for expressing the specific recommendation(s) in this report.

Required Disclosures

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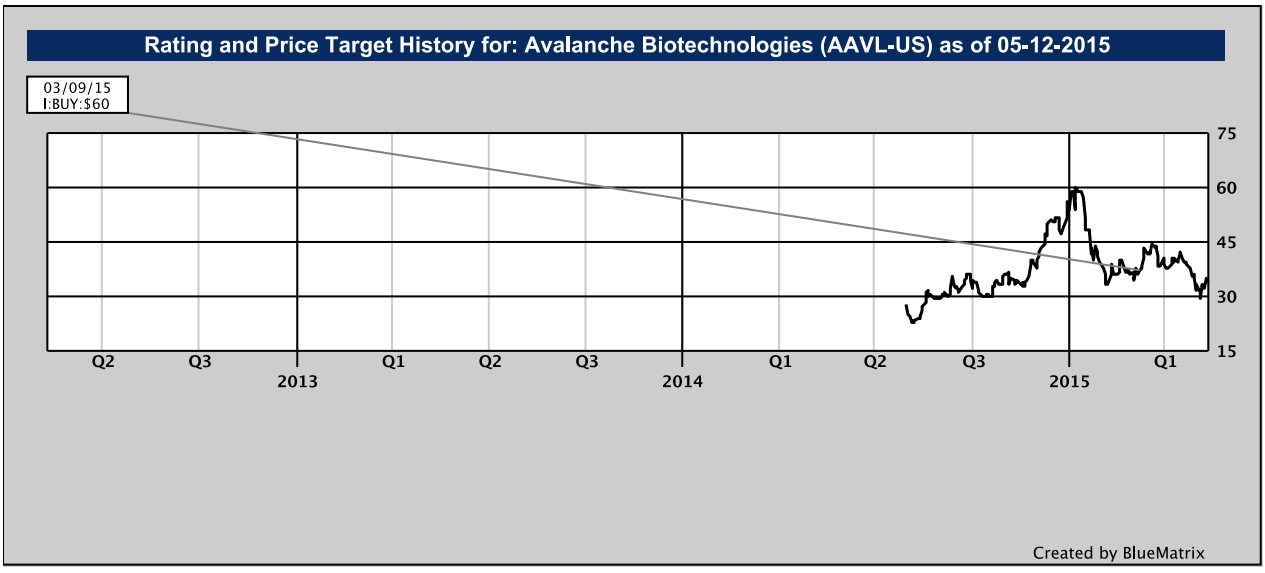

STRH Ratings System for Equity Securities

3 designations based on total returns* within a 12-month period**

- **Buy** – total return ≥ 15% (10% for low-Beta securities)***
- **Reduce** – total return ≤ negative 10% (5% for low Beta securities)
- **Neutral** – total return is within the bounds above
- **NR** – NOT RATED, STRH does not provide equity research coverage
- **CS** – Coverage Suspended

*Total return (price appreciation + dividends)
**Price targets are within a 12-month period, unless otherwise noted
***Low Beta defined as securities with an average Beta of 0.8 or less, using Bloomberg's 5-year average Beta

Legend for Rating and Price Target History Charts:
D = drop coverage
I = initiate coverage
T = transfer coverage

SunTrust Robinson Humphrey ratings distribution (as of 05/13/2015):

Coverage Universe			Investment Banking Clients Past 12 Months		
Rating	**Count**	**Percent**	**Rating**	**Count**	**Percent**
Buy	292	52.61%	Buy	105	35.96%
Neutral	251	45.23%	Neutral	49	19.52%
Sell/Reduce	12	2.16%	Sell/Reduce	2	16.67%

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