Ultragenyx Pharmaceutical, Inc. (RARE)

Q3 EPS: Pipeline Progressing

Buy

Price Target: $82.00
Prior: $82.00

Price (Nov. 10, 2014)	$41.16
52-Wk Range	$66.18-$33.36
Market Cap ($M)	$1,301
ADTV	406,087
Shares Out (M)	31.6
Short Interest Ratio/% Of Float	7.8%
TR to Target	99.2%

Cash Per Share	$5.16
Total Debt	$0.0
Cash And Equivalents ($M)	$201.0

	2013A	2014E		2015E	
		Curr.	Prior	Curr.	Prior
EPS Adjusted					
1Q	(3.36)	(0.85)A	(0.85)	(0.68)	(0.82)
2Q	(3.23)	(0.45)A	(0.45)	(0.59)	(0.62)
3Q	(2.58)	(0.50)A	(0.47)	(0.62)	(0.65)
4Q	(4.98)	(0.52)	(0.55)	(0.65)	(0.69)
FY	(14.15)	(2.32)	(2.23)	(2.53)	(2.77)
P/E	NM	NM		NM	
Revenue ($M)					
FY	$0	$0	$0	$0	$0
Consensus EPS					
FY	($11.25)	($2.07)A	($2.02)	($2.27)	($2.16)
Consensus Rev					
FY	$0	$0	$0	$0	$0
FYE Dec					

What's Incremental

RARE reported Q3 EPS of $(0.50), below consensus of $(0.46) and STRH of $(0.47), and provided 3 pipeline updates: 1) for SA-ER, FDA agreed to the Phase III design with the upper extremity strength composite as a primary endpoint with supporting PRO (GNEM-FAS) as a secondary, 2) triheptanoin in Glut1DS, Phase II inclusion criteria amended to include absence-only seizure patients, and 3) the KRN23 pediatric Phase II has reached its enrollment target of 30 patients.

Inclusion criteria broadened for triheptanoin Phase II in Glut1DS. RARE has decided to allow patients with refractory only absence seizures into the trial to enable faster enrollment and to target a broader patient population. While an effect in this patient subset may be harder to detect as the seizures can be highly short (few seconds) in duration and not obvious (no jerky motions), robust clinical methods to detect a change in frequency exist and have been utilized in demonstrating efficacy in other drugs (eg. ethosuximide, lamotrigine, valproic acid) for non-refractory absence-only epilepsy.

SA-ER for HIBM: FDA now on board with upper body strength composite. FDA has agreed to the pivotal Phase III primary endpoint of the upper extremity muscle strength composite with a supportive secondary endpoint from a patient-reported outcome measure (GNE myopathy functional activity scale). This development is highly favorable as the 6g dose demonstrated a benefit on this combination of endpoints in Phase II.

KRN23 for XLH pediatric trial fully enrolled. 30 patients were enrolled rapidly in only ~5 months (trial began in June 2014). High demand for the trial led to RARE asking some sites to stop enrolling. This corroborates our previous physician feedback that doctors believe in the efficacy and mechanism of KRN23, and are eager to treat their patients with the drug.

Q3 EPS; Our estimates are largely unchanged. Q3 GAAP R&D expenses were $12.9M, $0.3M below our estimate, while SG&A spend was $3.0M, $0.4M above our forecast. Based on these trends and our discussion with management, our out-year expense forecast is unchanged (implying sustained R&D investment as pipeline advances into clinical stages). RARE reported cash of $201.2M, sufficient to fund operations through 2016.

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

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

Weston Nichols, Ph.D.
212-303-4146
weston.nichols@suntrust.com

SEE PAGE 5 FOR REQUIRED DISCLOSURE INFORMATION

Figure 1: Ultragenyx's Potential Milestones

Product	Indication	Timing	Milestone
rhGUS	Mucopolysaccharidosis 7 (MPS 7/Sly)	Q4 2014/Q1 2015	Initiate Phase III trial
KRN23	X-linked hypophosphatemia (XLH)	H1 2015	Initiate Phase IIb (adult)
Triheptanoin	**Long-chain fatty acid oxidation disorders (LC-FAOD)**	**mid-15**	**Phase II interim data**
Triheptanoin	**Glucose transporter type-1 deficiency syndrome (Glut1 DS)**	**mid-15**	**Phase II interim data**
SA-ER	Hereditary inclusion body myopathy (HIBM)	mid-15	Initiation of Phase III trial
KRN23	**X-linked hypophosphatemia (XLH)**	**Q4 2015**	**Phase II (pediatric) interim data**
rhGUS	**Mucopolysaccharidosis 7 (MPS 7/Sly)**	**Q4 2015**	**Phase III results**

Sources: Company reports, STRH research

Figure 2: Q3 Variance Table

($thousands, except per share data)	Sep Q3 2014A	Sep 3Q 2014E	Variance A-E	Variance %	Y/Y %	Q/Q %
Revenue						
KRN23 revenue	$ -	$ -	$ -	N/A	N/A	N/A
rhGUS revenue	-	-	-	N/A	N/A	N/A
Triheptanoin revenue	-	-	-	N/A	N/A	N/A
SA-ER revenue	-	-	-	N/A	N/A	N/A
Total product revenue	**-**	**-**	**-**	N/A	N/A	N/A
Total profit share / royalty	**-**	**-**	**-**	N/A	N/A	N/A
Total Revenue	**$ -**	**$ -**	**$ -**	N/A	N/A	N/A
COGS			-	N/A	N/A	N/A
Gross profit	-	-	-	N/A	N/A	N/A
Operating expense						
R&D (GAAP)	12,854	13,199	(345)	-3%	90%	14%
SG&A (GAAP)	2,981	2,599	382	13%	198%	23%
Total operating expense (GAAP)	15,835	15,798	37	0%	104%	16%
Operating income (loss)	**(15,835)**	**(15,798)**	**(37)**	0%	104%	16%
Interest income		176	(176)	N/A	-100%	-100%
Interest expense	-	-	-	N/A	N/A	N/A
Other income (expense), net	$ -	$ (73)	$ 73	N/A	-100%	-100%
Total other (expense) income, net	(14)	103	(117)	836%	-98%	-118%
Net gain (loss) before taxes	**(15,849)**	**(15,695)**	**(154)**	1%	88%	17%
Income Tax Provision	-	-	-	N/A	N/A	N/A
Net income (loss) to common	**$ (15,849)**	**$ (15,695)**	**$ (154)**	1%	88%	17%
EPS (basic and diluted)	**$ (0.50)**	**$ (0.47)**	**$ (0.03)**	5%	-81%	11%
Weighted shares outstanding diluted	31,631	33,077	(1,446)	-5%	870%	5%

Sources: Company reports, STRH research

Revision Table

($thousands, except per share data)	FY14E		FY15E		FY16E		FY17E		FY18E		FY19E		FY20E	
	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior	New	Prior
Revenue														
KRN23 revenue	-	-	-	-	-	-	-	-	-	-	2,796	2,796	31,835	31,835
rhGUS revenue	-	-	-	-	-	-	617	617	13,962	13,962	32,172	32,172	47,022	47,022
Triheptanoin revenue	-	-	-	-	-	-	-	-	617	617	22,713	22,713	54,412	54,412
SA-ER revenue	-	-	-	-	-	-	-	-	953	953	5,245	5,245	13,248	13,248
Total product revenue	-	-	-	-	-	-	617	617	15,532	15,532	62,926	62,926	146,517	146,517
Total profit share / royalty	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**197**	**883**	**9,109**	**14,510**	**29,080**	**37,510**
Total Revenue	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 617**	**$ 617**	**$ 15,729**	**$ 16,415**	**$ 72,034**	**$ 77,436**	**$ 175,597**	**$ 184,027**
COGS	-	-	-	-	-	-	100	100	10,702	10,739	3,439	2,160	21,308	14,343
Gross profit	-	-	-	-	-	-	517	517	5,026	5,676	68,595	75,275	154,289	169,684
Operating expense	-		-		-		-		-		-		-	
R&D (GAAP)	46,891	47,236	67,652	67,652	86,232	86,232	95,923	95,923	102,332	102,332	109,223	109,223	116,232	116,232
SG&A (GAAP)	10,500	10,118	14,321	14,321	17,388	17,388	22,555	22,555	27,017	27,017	29,765	29,765	32,888	32,888
Stock-based compensation	8,645	3,866	14,983	5,669	16,503	7,223	18,009	8,002	19,554	9,102	21,007	10,099	23,005	11,092
Total operating expense (GAAP)	57,391	57,354	81,973	81,973	103,620	103,620	118,478	118,478	129,349	129,349	138,988	138,988	149,120	149,120
Operating income (loss)	**(57,391)**	**(57,354)**	**(81,973)**	**(81,973)**	**(103,620)**	**(103,620)**	**(117,961)**	**(117,961)**	**(124,323)**	**(123,673)**	**(70,393)**	**(63,713)**	**5,169**	**20,564**
Interest income	600	608	673	657	879	1,662	932	1,841	1,384	1,923	1,229	1,190	1,716	1,167
Interest expense	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other income (expense), net	$ (3,642)	$ (3,603)	$ -	$ (3,603)	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -	$ -
Total other (expense) income, net	(3,042)	(2,995)	673	(2,946)	879	1,662	932	1,841	1,384	1,923	1,229	1,190	1,716	1,167
Net gain (loss) before taxes	**(60,433)**	**(60,349)**	**(81,300)**	**(84,919)**	**(102,741)**	**(101,958)**	**(117,028)**	**(116,120)**	**(122,939)**	**(121,750)**	**(69,164)**	**(62,522)**	**6,885**	**21,730**
Income Tax Provision	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) to common	**$ (65,241)**	**$ (65,157)**	**$ (86,108)**	**$ (89,727)**	**$ (102,741)**	**$ (101,958)**	**$ (117,028)**	**$ (116,120)**	**$ (122,939)**	**$ (121,750)**	**$ (69,164)**	**$ (62,522)**	**$ 6,885**	**$ 21,730**
EPS (basic and diluted)	**$ (2.32)**	**$ (2.33)**	**$ (2.53)**	**$ (2.77)**	**$ (2.83)**	**$ (2.94)**	**$ (3.02)**	**$ (3.13)**	**$ (3.14)**	**$ (3.25)**	**$ (1.75)**	**$ (1.65)**	**$ 0.17**	**$ 0.56**
Weighted shares outstanding	-		-		-		-		-		-		-	
diluted	29,208	29,172	33,984	32,373	36,341	34,702	38,704	37,049	39,092	37,419	39,482	37,793	40,666	38,960

Sources: Company reports, STRH Research

Ultragenyx Pharmaceutical

(NASDAQ: RARE)

Consolidated Income Statement

($thousands, except per share data)

	FY 2013A	Mar Q1 2014A	Jun Q2 2014A	Sep Q3 2014A	Dec Q4 2014E	FY 2014E	FY 2015E	FY 2016E	FY 2017E	FY 2018E	FY 2019E	FY 2020E
Revenue												
KRN23 revenue booked by RARE	-	-	-	-	-	-	-	-	-	-	2,796	31,835
rhGUS revenue	-	-	-	-	-	-	-	-	617	13,962	32,172	47,022
Triheptanoin revenue	-	-	-	-	-	-	-	-	-	617	22,713	54,412
SA-ER revenue	-	-	-	-	-	-	-	-	-	953	5,245	13,248
Total product revenue	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 617**	**$ 15,532**	**$ 62,926**	**$ 146,517**
KRN23 U.S./Canada profit share/royalty	-	-	-	-	-	-	-	-	-	172	8,102	22,761
KRN23 E.U. royalty	-	-	-	-	-	-	-	-	-	-	883	6,020
SA-ER ex-U.S. royalty	-	-	-	-	-	-	-	-	-	25	124	298
Total profit share / royalty	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 197**	**$ 9,109**	**$ 29,080**
Total Revenue	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ -**	**$ 617**	**$ 15,729**	**$ 72,034**	**$ 175,597**
COGS	-					-	-	-	100	10,702	3,439	21,308
Gross profit	-	-	-	-	-	-	-	-	517	5,026	68,595	154,289
Operating expense												
R&D (GAAP)	27,829	8,353	11,239	12,854	14,445	46,891	67,652	86,232	95,923	102,332	109,223	116,232
SG&A (GAAP)	4,451	1,986	2,422	2,981	3,111	10,500	14,321	17,388	22,555	27,017	29,765	32,888
Stock-based compensation	657	795	946	3,393	3,511	8,645	14,983	16,503	18,009	19,554	21,007	23,005
Total operating expense (GAAP)	32,280	10,339	13,661	15,835	17,556	57,391	81,973	103,620	118,478	129,349	138,988	149,120
Operating income (loss)	**(32,280)**	**(10,339)**	**(13,661)**	**(15,835)**	**(17,556)**	**(57,391)**	**(81,973)**	**(103,620)**	**(117,961)**	**(124,323)**	**(70,393)**	**5,169**
Interest income	216	93	149	171	187	600	673	879	932	1,384	1,229	1,716
Interest expense	-	-	-	-	-	-	-	-	-	-	-	-
Other income (expense), net	(3,006)	(3,384)	(73)	(185)	-	(3,642)	-	-	-	-	-	-
Total other (expense) income, net	(2,790)	(3,291)	76	(14)	187	(3,042)	673	879	932	1,384	1,229	1,716
Net gain (loss) before taxes	**(35,070)**	**(13,630)**	**(13,585)**	**(15,849)**	**(17,369)**	**(60,433)**	**(81,300)**	**(102,741)**	**(117,028)**	**(122,939)**	**(69,164)**	**6,885**
Income Tax Provision	-	-	-	-	-	-	-	-	-	-	-	-
Net income (loss) attributable to common stockholders	**$ (42,338)**	**$ (18,438)**	**$ (13,585)**	**$ (15,849)**	**$ (17,369)**	**$ (65,241)**	**$ (86,108)**	**$ (102,741)**	**$ (117,028)**	**$ (122,939)**	**$ (69,164)**	**$ 6,885**
EPS (basic and diluted)	**$ (14.16)**	**$ (0.85)**	**$ (0.45)**	**$ (0.50)**	**$ (0.52)**	**$ (2.32)**	**$ (2.53)**	**$ (2.83)**	**$ (3.02)**	**$ (3.14)**	**$ (1.75)**	**$ 0.17**
Weighted shares outstanding diluted	3,763	21,582	30,056	31,631	33,562	29,208	33,984	36,341	38,704	39,092	39,482	40,666
Margin Analysis:												
Cost of goods sold	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	16%	69%	5%	15%
KRN23	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0%	12%	20%	25%
rhGUS	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0%	1%	2%	14%
Triheptanoin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0%	4%	8%	10%
SA-ER	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	0%	4%	8%	10%
Gross margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	31%	95%	85%
R&D (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	651%	152%	66%
SG&A (GAAP)	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	172%	41%	19%
Total operating expense	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	822%	193%	85%
Operating margin	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Income tax provision	0%	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	N/A	N/A	N/A	N/A
Y/Y change:												
Total revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	2447%	358%	144%
KRN23 revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1039%
rhGUS revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	2161%	130%	46%
Triheptanoin revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	3584%	140%
SA-ER revenue	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	450%	153%
Total profit share / royalty	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	4534%	219%
KRN23 U.S. / Canada profit share / royalty	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	4622%	181%
KRN23 E.U. royalty	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	582%
SA-ER ex-U.S. royalty	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	395%	141%
R&D (GAAP)	120%	N/A	N/A	N/A	N/A	68%	44%	27%	11%	7%	7%	6%
SG&A (GAAP)	33%	N/A	N/A	N/A	N/A	136%	36%	21%	30%	20%	10%	10%
Total operating expense	102%	N/A	N/A	N/A	N/A	78%	43%	26%	14%	9%	7%	7%
Operating income	102%	N/A	N/A	N/A	N/A	78%	43%	26%	14%	5%	-43%	-107%
Net income (loss)	116%	N/A	N/A	N/A	N/A	54%	32%	19%	14%	5%	-44%	-110%
GAAP EPS (diluted)	-10%	N/A	N/A	N/A	N/A	-84%	9%	12%	7%	4%	-44%	-110%
Shares outstanding - GAAP	173%	N/A	N/A	N/A	N/A	676%	16%	7%	7%	1%	1%	3%

Sources: Company reports, STRH Research

Company Description
Ultragenyx is developing therapies for ultra-rare diseases, with 4 drugs in development for 5 different indications. The company focuses on identification, acquisition, development, and commercialization of new products for the treatment of ultra-rare diseases with a focus on metabolic, genetic and under-served diseases.

Investment Thesis
RARE boasts a portfolio of mid- to late-stage clinical assets to tackle genetic ultra-orphan diseases. With 4 clinical stage therapies developed for 5 indications, we anticipate a slew of data catalysts in 2015, with potential product approvals in 2017/18. **Physician feedback suggests all programs have good clinical probabilities of success.**

Valuation and Risks
Valuation:
We arrive at our 12-month price target of $82 by means of a sum-of-the-parts discounted cash flow analysis, which ascribes $23.60/share to KRN23, $8.10/share to rhGUS, $42.90/share to triheptanoin, $2.00/share to SA-ER and $5.72/share in cash, with the following assumptions: we assign KRN23 a 75% probability of success, rhGUS an 85% probability of success, triheptanoin a 60% probability of success and SA-ER a 50% probability of success. We assign a discount rate of 10% to KRN23, triheptanoin, and SA-ER, and a 9% discount rate to rhGUS. We assume a 2% terminal growth rate for KRN23, triheptanoin, and SA-ER, and a 3% terminal growth rate for rhGUS

The primary investment risks for Ultragenyx include the following:

- Clinical development risk: There is some uncertainly as to whether earlier stage experiments (preclinical, Phase I, or historical case reports) will translate into efficacy in Phase III.
- Regulatory risk: Even upon successful clinical data, the FDA may not view the results as worthy of regulatory approval for commercial sale. In particular, we highlight the risk of the FDA not accepting certain biomarker endpoints for the accelerated approval pathway.
- Commercial risk: Each product may fail to achieve revenues in line with our peak estimates in the commercial market.
- Competitive risk: The emergence of competing therapies may reduce Ultragenyx's market share.
- Partnership risk: Ultragenyx relies on partnerships for some of its therapies, KRN23 in particular. KHK manufactures and will commercialize the product in the E.U., thus Ultragenyx is vulnerable to shortcomings of their partners.
- Management risk: Ultragenyx has assembled a team of all-stars from the rare disease world, especially the CEO, Emil Kakkis. If certain employee were to leave at inopportune times, it may damage the company's chances of success.
- Financing risk: As a development stage company, Ultragenyx is not profitable and may not turn profitable in the near future. Future financings may be required to develop drugs, which may dilute existing shareholders.

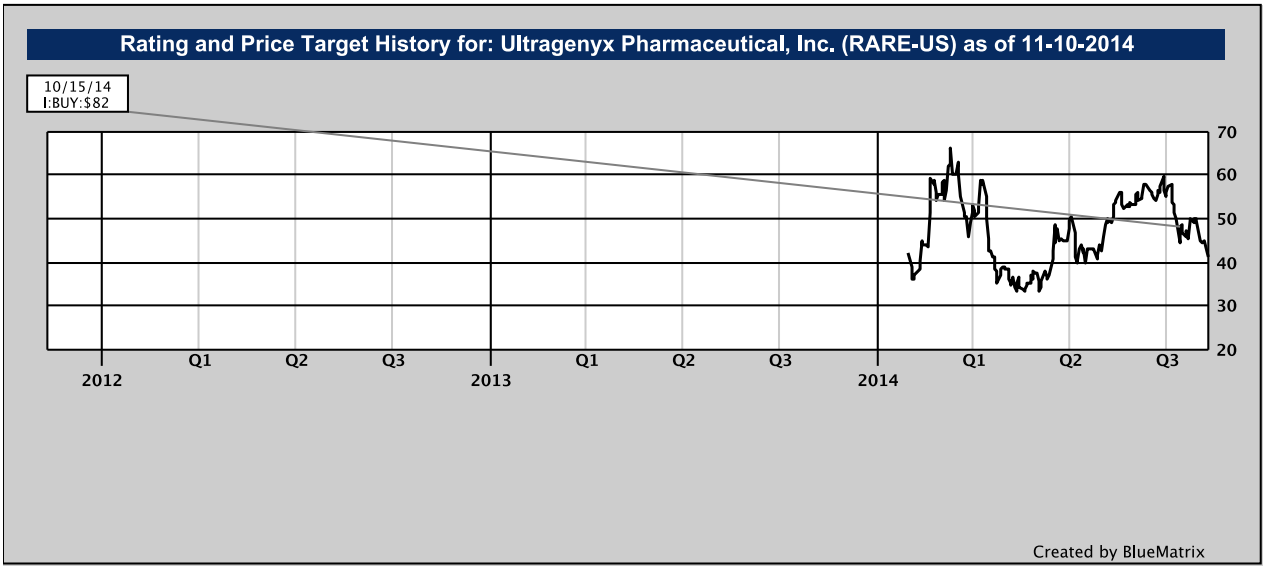
Companies Mentioned in This Note
Ultragenyx Pharmaceutical, Inc. (RARE, $41.16, Buy)

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
SunTrust Robinson Humphrey, Inc. makes a market in the following companies at the time of this report: RARE, RARE-US

Analyst compensation is based upon stock price performance, quality of analysis, communication skills, and the overall revenue and profitability of the firm, including investment banking revenue.

As a matter of policy and practice, the firm prohibits the offering of favorable research, a specific research rating or a specific target price as consideration or inducement for the receipt of business or compensation. In addition, associated persons preparing research reports are prohibited from owning securities in the subject companies.



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 11/11/2014):

Coverage Universe			Investment Banking Clients Past 12 Months		
Rating	**Count**	**Percent**	**Rating**	**Count**	**Percent**
Buy	283	54.42%	Buy	84	29.68%
Neutral	230	44.23%	Neutral	41	17.83%
Sell/Reduce	7	1.35%	Sell/Reduce	0	0.00%

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