Relypsa (RLYP)

Q1 Financials in Line; Phase 1 Shows Rapid Drop of Hyperkalemia & Q3 NDA Submission On Track; Reiterate OUTPERFORM and Increasing PT to $57 for Time

- **Q1 financials were in line with our estimates.** Relypsa reported no revenues and a net loss of $(0.54) for Q1 versus our $(0.54). R&D expenses were $10.9 million vs our $11.1 million. General and administrative expenses for Q1 were $4.8 million vs our $4.3 million. Relypsa ended Q1 2014 with about $78.9 million in cash. We have adjusted our model based on Q1 financials and we project runway into 2015.
- **Relypsa's Phase I patiromer trial met its primary endpoint of early onset reduction in mean potassium levels; data further supports Q3 NDA submission**. In a Phase I open-label, single-arm trial, Relypsa reported that following the first dosing of a twice-daily dosing regimen of patiromer, mean potassium levels were reduced at all-time points measured during a 48-hour observation period ($p < 0.001$ at 48 hrs). The reduction in mean potassium levels reached statistical significance as early as 7 hours post drug administration and were sustained at all evaluation points thereafter. Mean serum potassium was reduced from 5.93 mEq/L at baseline to a maximum mean reduction of 0.83 mEq/L. No serious adverse events were reported and no drop-outs due to adverse events were recorded. Recall this trial was requested by the FDA to fill out the pharmacokinetic / pharmacodynamics profile of patiromer. Although we do not view this positive data as impactful to RLYP valuation near-term, we find that these results are likely to increase the chances of patiromer's FDA approval.
- **Management continues to deliver, in our view.** The company will file an NDA for patiromer in Q3 2014. The FDA has 60 days to respond to an NDA submission and the company anticipates potential FDA acceptance in Q4 2014. The company estimates an FDA advisory committee (if necessary) could potentially occur in Q2:15, followed by potential approval in Q3:15 and U.S. launch in Q4:15. With regulatory and commercial success, we project gross peak annual U.S. sales for patiromer could reach about $1.4 billion.
- **We reiterate our OUTPERFORM rating and are increasing our 12-month price target to $57 due to time value.** Our price target is calculated based on sum-of-parts for each drug/indication combination using a 30% annual discount from our peak annual revenues projections and 1-10x multiple, depending on stage of development to reflect risk followed by a 365-day projection for time value.

FYE Dec	2013A	2014E			2015E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$0.0A	$0.0A		$0.0E	$0.0E		N/AE
Q2 Jun	0.0A	0.0E		0.0E	0.0E		N/AE
Q3 Sep	0.0A	0.0E		0.0E	0.0E		N/AE
Q4 Dec	0.0A	0.0E		0.0E	6.5E		N/AE
Year*	**$0.0A**	**$0.0E**		**$0.0E**	**$6.5E**		**$8.2E**
Change	--	--			--		
	2013A	**2014E**			**2015E**		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$(4.92)A	$(0.54)A		($0.56)E	$(0.85)E		N/AE
Q2 Jun	(3.78)A	(0.57)E		(0.62)E	(0.86)E	(0.85)E	N/AE
Q3 Sep	(1.30)A	(0.69)E		(0.71)E	(0.87)E	(0.86)E	N/AE
Q4 Dec	(0.68)A	(0.84)E		(0.80)E	(0.84)E	(0.83)E	N/AE
Year*	**($22.42)A**	**($2.66)E**	**($2.65)E**	**($2.69)E**	**$(3.41)E**	**$(3.39)E**	**($3.11)E**
P/E	--	--			--		
Change	--	--			--		

Consensus estimates are from Thomson First Call.
** Numbers may not add up due to rounding.*

May 13, 2014

Price
$21.39

Rating
OUTPERFORM

12-Month Price Target
$57 **(from $56)**

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Company Information	
Shares Outst (M)	33.8
Market Cap (M)	$724
52-Wk Range	$11.90 - $52.74
Book Value/sh	$4.03
Cash/sh	$4.71
Enterprise Value (M)	$866
LT Debt/Cap %	7

Company Description

Relypsa is an emerging pharmaceutical company focused on the development and commercialization of treatments for renal, cardiovascular, and metabolic disorders. Patiromer, a non-absorbed polymer, is the lead drug candidate and is for the treatment of hyperkalemia.

Source: Thomson Reuters

Investment Thesis: Relypsa is an emerging pharmaceutical company focused on the development and commercialization of cutting-edge treatments for renal, cardiovascular, and metabolic disorders. Its polymer drug discovery platform was in-licensed from Ilypsa, Inc., a subsidiary of Amgen (AMGN). Patiromer is the lead drug candidate emerging from this platform and is a non-absorbed, optimized potassium-binding polymer which is dosed twice daily as an oral suspension powder to normalize hyperkalemia in patients with chronic kidney disease (CKD) and/or heart failure (HF). Hyperkalemia (HK), a chronic condition characterized by excessive potassium, typically occurs in CKD and HF patients due to the body's inability to properly clear potassium. Furthermore, renin-angiotensin-aldosterone system inhibitors (RAASi), the standard-of-care for CKD and HF, can actually cause hyperkalemia themselves. Due to the lack of effective, safe, and tolerable treatments for hyperkalemia, treatment guidelines recommend reducing or discontinuing RAASi therapy if hyperkalemia develops—despite their protective effects on the kidney. This situation has created an unmet medical need for CKD and HF patients. In our view, patiromer has the potential to be best-in-class and the first breakthrough treatment for hyperkalemia since 1958. Compared to the only currently approved treatment for hyperkalemia, Kayexalate (an absorbed polymer), the physical and chemical properties of patiromer confer several advantages, including better binding capacity, tolerability and compliance. In fact, Kayexalate has never shown statistically significant reductions in serum potassium levels in prospective clinical trials. In addition, its poor tolerability profile makes it unsuitable for chronic administration. In contrast, patiromer was shown to be effective at lowering serum potassium levels into the normal range while also reducing the incidence of recurrent hyperkalemia with chronic dosing in the Phase 3 and Phase 2b programs. Given the clinical profile of patiromer, we believe it has the potential to fill an unmet need for CKD and HF patients with mild or moderate-to-severe hyperkalemia as well those on a suboptimal dose of a RAASi due to recurrent hyperkalemia. In the U.S., we estimate there are about 2.4 million CKD and HF patients who would be immediately eligible for patiromer treatment, with additional opportunities to further expand and grow the market. We anticipate the company will file an NDA in Q3:14, setting the stage for potential approval and launch in H2:15. With a small specialty sales force of about 100 reps, we project peak annual sales of patiromer could reach about $1.4 billion in the U.S. alone.

Relypsa's Phase I patiromer trial met its primary endpoint of early onset reduction in mean potassium levels; data further supports Q3 NDA submission, in our view. In a Phase I open-label, single-arm trial, Relypsa reported that following the first dosing of a twice-daily dosing regimen of patiromer, mean potassium levels were reduced at all-time points measured during a 48-hour observation period ($p < 0.001$ at 48 hrs). The reduction in mean potassium levels reached statistical significance as early as 7 hours post drug administration and were sustained at all evaluation points thereafter. Mean serum potassium was reduced from 5.93 mEq/L at baseline to a maximum mean reduction of 0.83 mEq/L. No serious adverse events were reported and no drop-outs due to adverse events were recorded. Recall this trial was requested by the FDA to fill-out the pharmacokinetic / pharmacodynamics profile of patiromer. Although we do not view this positive data as impactful to RLYP valuation near-term, we find that these results are likely to increase the chance of patiromer's FDA approval.

Figure 1: MODEL UPDATE

Relypsa, Inc. (RLYP:NASDAQ) — **Wedbush Securities, Inc.**
Historical and Projected Income Statement — *Liana Moussatos, PhD*
(In thousands except per share data)

	2013A	2014E					2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
	FY:13A	Q1A	Q2E	Q3E	Q4E	FY:14E	FY:15E	FY:16E	FY:17E	FY:18E	FY:19E	FY:20E	FY:21E	FY:22E	FY:23E	FY:24E	FY:25E
Revenues:																	
Patiromer	-	-	-	-	-	-	6,506	83,650	245,425	582,201	1,005,874	1,304,943	1,437,453	1,474,632	1,487,033	1,490,764	1,337,741
Total Net Product Revenues	-	-	-	-	-	-	6,506	83,650	245,425	582,201	1,005,874	1,304,943	1,437,453	1,474,632	1,487,033	1,490,764	1,337,741
Grant Revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Collaborative Licensing and Development Revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	$ -	$ -	$ -	$ -	$ -	$ -	$ 6,506	$ 83,650	$ 245,425	$ 582,201	$ 1,005,874	$ 1,304,943	$ 1,437,453	$ 1,474,632	$ 1,487,033	$ 1,490,764	$ 1,337,741
Total COGS	-	-	-	-	-	-	5,205	59,745	146,137	278,263	363,186	317,427	287,491	294,926	297,407	298,153	267,548
Gross Margin	$ -	$ -	$ -	$ -	$ -	$ -	$ 1,301	$ 23,905	$ 99,288	$ 303,938	$ 642,688	$ 987,516	$ 1,149,962	$ 1,179,705	$ 1,189,626	$ 1,192,611	$ 1,070,193
Operating Expenses:																	
R&D	58,971	10,909	11,127	11,350	11,577	44,963	48,669	52,681	57,023	61,724	66,812	72,320	78,281	84,734	91,719	99,279	107,463
SG&A	11,940	4,795	7,593	11,544	16,659	40,591	68,320	71,094	73,981	76,985	80,470	104,395	114,996	117,971	118,963	119,261	107,019
Acquired in-process R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	$ 70,911	$ 15,704	$ 18,720	$ 22,894	$ 28,236	$ 85,554	$ 116,989	$ 123,775	$ 131,004	$ 138,709	$ 147,282	$ 176,715	$ 193,277	$ 202,704	$ 210,681	$ 218,540	$ 214,482
Operating Income (Loss)	(70,911)	(15,704)	(18,720)	(22,894)	(28,236)	(85,554)	(115,688)	(99,870)	(31,716)	165,229	495,406	810,801	956,685	977,001	978,945	974,071	855,711
Interest Income / (Expense), net	(1,481)	27	(236)	(182)	(163)	(555)	(486)	(326)	(481)	(407)	77	1,025	2,375	3,853	5,349	6,845	8,324
Other Income / (Expense), net	(1,453)	(391)	(399)	(402)	(400)	(1,591)	(1,596)	(1,597)	(1,597)	(1,597)	(1,597)	(1,597)	(1,597)	(1,597)	(1,597)	(1,597)	(1,597)
Income Before Income Taxes	$ (73,845)	$ (16,068)	$ (19,355)	$ (23,478)	$ (28,799)	$ (87,700)	$ (117,770)	$ (101,793)	$ (33,794)	$ 163,225	$ 493,886	$ 810,228	$ 957,463	$ 979,257	$ 982,697	$ 979,319	$ 862,437
Deemed Dividend to preferred stockholders	(7,336)																
(Provision)/benefit for Income Taxes	-	-	-	-	-	-	-	-	(199)	(31,596)	(192,615)	(315,989)	(373,411)	(381,910)	(383,252)	(381,934)	(336,351)
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.3%	13.5%	39.0%	39.0%	39.0%	39.0%	39.0%	39.0%	39.0%
Net Income (Loss)	$ (81,181)	$ (16,068)	$ (19,355)	$ (23,478)	$ (28,799)	$ (87,700)	$ (117,770)	$ (101,793)	$ (33,993)	$ 131,629	$ 301,270	$ 494,239	$ 584,052	$ 597,347	$ 599,445	$ 597,384	$ 526,087
Stock-based compensation		1,998	1,875	1,875	1,875	7,623	7,560	7,551	7,549	7,549	7,549	7,549	7,549	7,549	7,549	7,549	7,549
EPS	$ (22.42)	$ (0.61)	$ (0.63)	$ (0.75)	$ (0.90)	$ (2.90)	$ (3.63)	$ (3.11)	$ (1.16)	$ 3.42	$ 7.96	$ 12.97	$ 15.12	$ 15.23	$ 15.05	$ 14.78	$ 12.80
GAAP EPS	$ (22.42)	$ (0.54)	$ (0.57)	$ (0.69)	$ (0.84)	$ (2.66)	$ (3.41)	$ (2.90)	$ (0.95)	$ 3.62	$ 8.16	$ 13.17	$ 15.32	$ 15.43	$ 15.25	$ 14.96	$ 12.98
Weighted Average Shares Outstanding	3,620	29,710	33,845	33,995	34,145	32,924	34,520	35,120	35,720	36,320	36,920	37,520	38,120	38,720	39,320	39,920	40,520
Cash	$94,759	$76,917	$159,315	$133,694	$102,790	$102,790	($32,502)	($165,397)	($215,509)	($100,501)	$185,644	$664,520	$1,242,742	$1,841,048	$2,440,175	$3,037,605	$3,602,127
Cash Per Share	$26.17	$2.66	$4.71	$3.93	$3.01	$3.12	($0.94)	($4.71)	($6.03)	($2.77)	$5.03	$17.71	$32.60	$47.55	$62.06	$76.09	$88.90
Net Cash	$ 84,418	$ 65,975	$142,231	$118,508	$89,502	$ 91,994	$ (43,298)	$ (176,193)	$ (226,305)	$ (111,297)	$ 175,048	$ 653,724	$ 1,231,946	$ 1,830,252	$ 2,429,379	$ 3,026,809	$ 3,591,331
Net Cash Per Share	$23.32	$2.22	$4.20	$3.49	$2.62	$2.79	($1.25)	($5.02)	($6.34)	($3.06)	$4.74	$17.42	$32.32	$47.27	$61.78	$75.82	$88.63
Cash Burn (Generation)	($3,604)					$28,769	$172,092	$169,695	$86,912	($78,208)	($249,546)	($441,876)	($541,422)	($561,506)	($562,327)	($560,630)	($527,722)

Source: Company data, Wedbush Securities, Inc.

Q1 financials were in line with our estimates. Relypsa reported no revenues and a net loss of $(0.54) for Q1 versus our $(0.54). R&D expenses were $10.9 million vs our $11.1 million. General and administrative expenses for Q1 were $4.8 million vs our $4.3 million. Relypsa ended Q1 2014 with about $78.9 million in cash. We have adjusted our model based on Q1 financials and we project runway into 2015.

Figure 2: MILESTONES (*our estimates)

Q3:14	**PATIROMER NDA SUBMISSION**
Q2:15*	**POTENTIAL FDA ADVISORY COMMITTEE FOR PATIROMER (*IF NECESSARY)**
Q3:15	**POTENTIAL FDA APPROVAL OF PATIROMER**
Q4:15*	**POTENTIAL U.S. LAUNCH OF PATIROMER**
2014/2015*	POTENTIAL PATIROMER PARTERSHIP(S)

Source: Company data, Wedbush Securities, Inc.

Management continues to deliver, in our view. The company will file an NDA for patiromer in Q3 2014. The FDA has 60 days to respond to an NDA submission and the company anticipates potential FDA acceptance in Q4 2014. The company estimates an FDA advisory committee (if necessary) could potentially occur in Q2:15, followed by potential approval in Q3:15 and U.S. launch in Q4:15. With regulatory and commercial success, we project gross peak annual U.S. sales for patiromer could reach about $1.4 billion.

Figure 3: VALUATION

RLYP Product Pipeline Valuation		Eligible #	Pricing	Gross Peak Sales	Net Peak Revs	Peak		Estimated/Actual	Discount	Estimate	Fair Value
Product	Indication	Patients	$/Patient	($000)	($000)	Penetration	Multiple	Launch	Rate	Fair Value	per Share
Patiromer (US)	Hyperkalemia (moderate to severe)	3,790,000	$6,324	$1,084,250	$1,084,250	15%	7	11/4/2015	30%	$1,482,547	$43.80
Patiromer (US)	Hyperkalemia (mild / suboptimal RAASi)	13,760,000	$6,120	$419,159	$419,159	2%	7	11/4/2015	30%	$440,874	$13.03
Patiromer (EU)	Hyperkalemia (moderate to severe)	2,526,667	$5,059	$417,637	$83,527	10%	7	11/3/2016	30%	$63,159	$1.87
Patiromer (EU)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	$4,896	$161,454	$32,291	1%	7	11/3/2016	30%	$18,782	$0.55
Patiromer (ROW)	Hyperkalemia (moderate to severe)	2,526,667	$4,047	$231,307	$23,131	8%	7	11/3/2017	30%	$13,454	$0.40
Patiromer (ROW)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	$3,917	$89,421	$8,942	1%	7	11/3/2017	30%	$4,001	$0.12
RLY-6002	T2D	139,900,146	$1,446	$1,154,672	$540,678	1%	1	1/2/2024	30%	$11,581	$0.34
We use multiples to account for clinical and regulatory risk at various stages of development.								Stock	MktCap		Upside
1: in preclinical testing	6: in Phase 3				12-month Price Target			$56.83	$1,923,421		166%
2: passed preclinical	7: Phase 3 data					Total Pipeline Value		$60.11	$2,034,398		
3: IND filing/stable mature product	8: regulatory review					Current Cash		$2.33	$78,917		
4: Phase 1 data	9: approved					Current Price		$21.39	$723,952		
5: Phase 2 data	10: launched										

Source: Company data, Wedbush Securities, Inc.

We reiterate our OUTPERFORM rating and are increasing our 12-month price target to $57 due to time value. Our price target is calculated based on sum-of-parts for each drug/indication combination using a 30% annual discount from our peak annual revenues projections and 1-10x multiple, depending on stage of development to reflect risk followed by a 365-day projection for time value.

Risks to attainment of our fair value include: 1) Clinical – There is risk that results from the ongoing Phase 1 onset-of-action study are negative, but we view this is unlikely.; 2) Regulatory – Although the Phase 3 program was successful and conducted under a special protocol assessment (SPA), the FDA may fail to approve patiromer in a timely fashion, if at all.; 3) Manufacturing – Relypsa relies on third-party suppliers to manufacture patiromer and there is risk that those parties may not meet their obligations. In addition, they may not be able to successfully scale up manufacturing in a timely and cost efficient manner.; 4) Commercial – As with all new product launches, initial sales of patiromer could be slower than anticipated and call into question its ultimate sales potential. Furthermore, patiromer could face competition from potential new drugs for hyperkalemia including ZS Pharma's late-stage candidate, ZS-9.; 5) Financing – The company ended Q1 2014 with about $78.9MM in cash and investments. We project runway into Q4 2015—when we estimate potential FDA approval of patiromer. Therefore, we believe Relypsa will likely need to raise additional funds in order to commercially launch patiromer (and/or work with a strategic partner for primary care and/or exUS commercialization) and to ultimately reach profitability which we model to occur in 2018.

Analyst Biography

Ms. Moussatos is a Managing Director, Equity Research responsible for the coverage of stocks in the Emerging Pharmaceuticals sector. Liana joined Wedbush from Pacific Growth Equities where she was a Senior Research Analyst. Prior to that she came from UBS Global Asset Management where she was Director and Portfolio Manager of the UBS Global Biotech Funds for five years. Previously Liana was with Bristol-Meyers Squibb where she was a manager in University and Government Licensing External Science and Technology and she also worked with Sloan-Kettering Cancer Institute in the Office of Industrial Affairs and the National Cancer Institute in the Office of Technology Development.

Liana received a B.S. in Entomology and a M.S. in Zoology and Biochemistry from Clemson University and a Ph.D. in Plant Pathology from the University of California Davis and completed a postdoctoral research fellowship in Cellular and Molecular Physiology at the Yale School of Medicine.

Liana's Edge: Liana's industry and buy-side experience provide depth in her understanding of what investors need to know along with her 13 years experience in following healthcare stocks. Her pipeline valuation includes all drug candidates / disease indications in active development and provides investors with a stock value for each program.

Analyst Certification
I, Liana Moussatos, Ph.D., certify that the views expressed in this report accurately reflect my personal opinion and that I have not and will not, directly or indirectly, receive compensation or other payments in connection with my specific recommendations or views contained in this report.

Disclosure information regarding historical ratings and price targets is available at http://www.wedbush.com/ResearchDisclosure/DisclosureQ114.pdf

Investment Rating System:
Outperform: Expect the total return of the stock to outperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Neutral: Expect the total return of the stock to perform in-line with the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.
Underperform: Expect the total return of the stock to underperform relative to the median total return of the analyst's (or the analyst's team) coverage universe over the next 6-12 months.

The Investment Ratings are based on the expected performance of a stock (based on anticipated total return to price target) relative to the other stocks in the analyst's coverage universe (or the analyst's team coverage).*

Rating Distribution (as of March 31, 2014)	**Investment Banking Relationships (as of March 31, 2014)**
Outperform:54% Neutral: 43% Underperform: 3%	Outperform:22% Neutral: 2% Underperform: 0%

The Distribution of Ratings is required by FINRA rules; however, WS' stock ratings of Outperform, Neutral, and Underperform most closely conform to Buy, Hold, and Sell, respectively. Please note, however, the definitions are not the same as WS' stock ratings are on a relative basis.

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Wedbush Equity Research Disclosures as of May 13, 2014

Company	Disclosure
Relypsa	1,3,4,5,7

Research Disclosure Legend
1. WS makes a market in the securities of the subject company.
2. WS managed a public offering of securities within the last 12 months.
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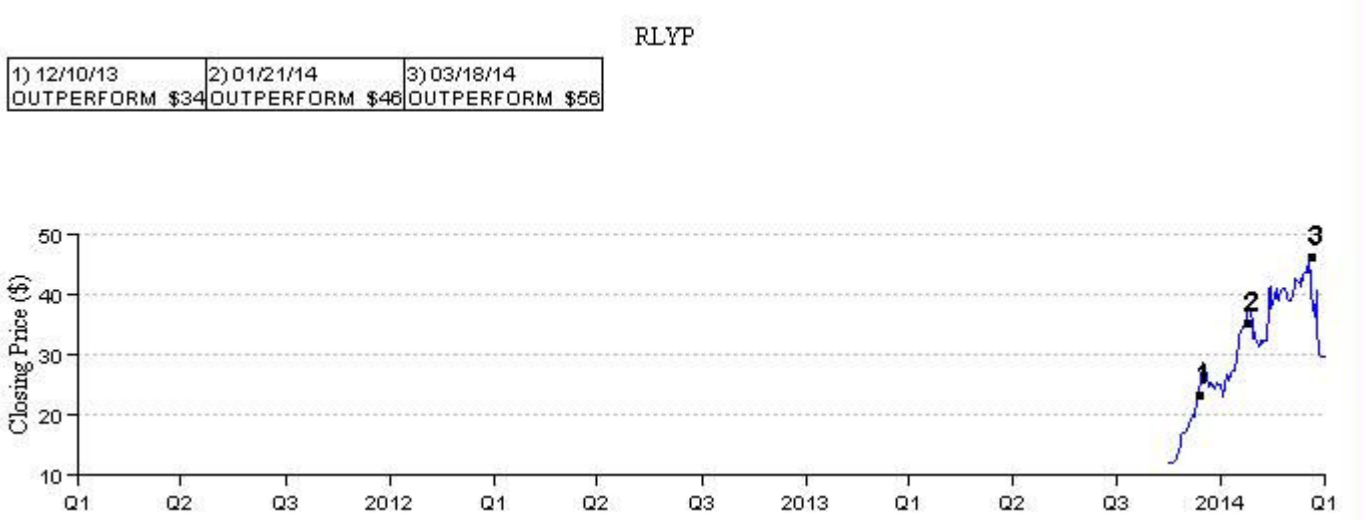

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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