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Relypsa (RLYP)

Corporate Update Includes Release of New Clinical Data and Manufacturing Progress; Reiterate OUTPERFORM and Rolling Over 12-month PT to \$46

- Last week, Relypsa released new RAASi data from the pivotal Phase 3 trial testing patiromer for the treatment of hyperkalemia. Results on the secondary endpoints showed that significantly more placebo patients required dose modification of their RAASi therapies (62%) than patiromer patients (6%), p<0.001; with more patiromer patients (94%) still on RAASi medication at the end of the trial than placebo patients (48%), p<0.001 (please see page 2 for more detailed trial data). In our view, these data highlight the benefits of chronic patiromer treatment. Although renin-angiotensin-aldosterone system inhibitors (RAASi) are highly effective at treating chronic kidney disease and heart failure, they can also cause hyperkalemia resulting in sub-optimal doses or complete discontinuation. The patiromer data suggests that a significant proportion of patients can remain on their optimal RAASi dose with patiromer controlling their serum potassium levels. We believe this could potentially lead to better clinical outcomes as well as healthcare savings over the long-term, although additional data would be needed to support this. We remain encouraged by the patiromer data released to date as we are not aware of any other drugs that have been shown to work chronically in controlling serum potassium while exhibiting an acceptable tolerability profile.
- The company also confirmed that it is on track to submit the patiromer NDA to the FDA in Q3:14. In addition, it announced a multi-year manufacturing and supply agreement with Lanxess Corporation to ensure commercial quantities of the patiromer API.
- **Next:** We anticipate data from the Phase 1 onset-of-action trial in H1:14, which would be supportive of a potential NDA filling in Q3:14. We estimate an FDA advisory committee (if necessary) would occur in Q2:15, followed by potential approval in Q3:15 and U.S. launch in Q4:15.
- We reiterate our OUTPERFORM rating and are converting to a 12-month price target of \$46 from our previous present day fair value of \$34. By rolling our previous \$34 fair value forward by one year at a 30% annual discount rate, we arrive at our 12-month price target of \$46. 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.

FYE Dec	2012A		2013E			2014E	
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar		\$0.0A			\$0.0E		
Q2 Jun		0.0A			0.0E		
Q3 Sep		0.0A			0.0E		
Q4 Dec		0.0E			0.0E		
Year*	\$0.0A	\$0.0E			\$0.0E		
Change							
	2012A		2013E			2014E	
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar		\$(4.92)A			\$(0.53)E		
Q2 Jun		(3.78)A			(0.44)E		
Q3 Sep		(1.30)A			(0.31)E		
Q4 Dec		(0.76)E			(0.38)E		
Year*	\$(8.36)A	(\$10.76)E			(\$1.65)E		
P/E							
Change					I		

January 21, 2014

Price

\$34.60

Rating

OUTPERFORM

12-Month Price Target \$46 (from \$34)

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Company Information	
Shares Outst (M)	28.7
Market Cap (M)	\$993
52-Wk Range	\$11.90 - \$35.70
Book Value/sh	\$0.74
Cash/sh	\$2.87
Enterprise Value (M)	\$1055
LT Debt/Cap %	21

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

Consensus estimates are from Thomson First Call.

* Numbers may not add up due to rounding.

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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 llypsa, 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, reninangiotensin-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.

Figure 1: ANTICIPATED MILESTONES (*our estimates)

H1:14	PATIROMER PHASE 1 ONSET-OF-ACTION RESULTS
H1:14	COMPLETION OF CMC ACTIVITIES SUPPORTIVE OF NDA
Q3:14	PATIROMER NDA SUBMISSION
Q2:15	POTENTIAL FDA ADVISORY COMMITTEE FOR PATIROMER
Q3:15	POTENTIAL FDA APPROVAL OF PATIROMER (*IF NECESSARY)
Q4:15	POTENTIAL U.S. LAUNCH OF PATIROMER
2014/2015*	POTENTIAL PATIROMER PARTERSHIP(S)

Source: Company reports and Wedbush Pacgrow Life Sciences

Next: We anticipate data from the Phase 1 onset-of-action trial in H1:14, which would be supportive of a potential NDA filing in Q3:14. We estimate a FDA advisory committee (if necessary) would occur in Q2:15, followed by potential approval in Q3:15 and U.S. launch in Q4:15.

PIVOTAL PHASE 3 STUDY (RLY5016-301) (*New data in italics)

Phase 3 Study Design. RLY5016-301 is a two-part, pivotal Phase 3 study that was conducted under a Special Protocol Assessment (SPA). The two parts of the study will each serve as a pivotal trial.

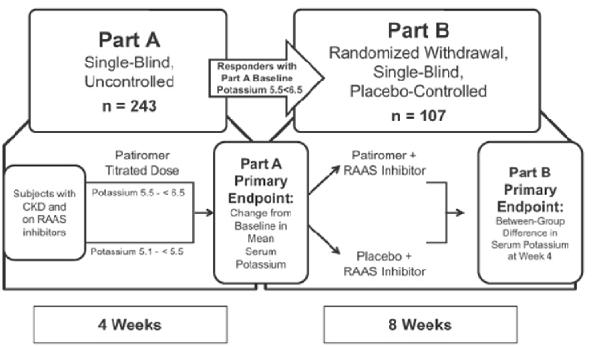
Part A: The first part of the study was a 4-week, single arm, single-blind trial that enrolled 240 subjects. Patients with a baseline serum potassium level of 5.1 to <5.5 mEq/L were placed into Dose Group 1 while patients with baseline serum potassium of 5.5 to ≤6.5 mEq/L were place into Dose Group 2. Because patients entering the study were hyperkalemic, it was deemed unethical to use a placebo control arm in Part A. The primary endpoint for Part A was the change from baseline to week 4 in mean serum potassium levels with a target reduction of at least 0.7 mEq/L (p<0.05) considered to be clinically meaningful by the FDA.

Part B: The second part of the study was an 8-week, parallel group, single-blind placebo-controlled randomized withdrawal trial that enrolled 80 subjects. Patients from Part A with a baseline serum potassium level ≥5.5 mEq/L and who were defined as responders at the end of Part A were eligible to be randomized into Part B. In the event of recurrent hyperkalemia, patients in the patiromer group increased their patiromer dose, while patients in the placebo group decreased their RAASi dose. The primary endpoint for Part B was the difference between the patiromer and placebo groups in the change in serum potassium levels. *The secondary endpoints included*



(1) the proportion of subjects requiring any dose modification of RAASi therapies (i.e. down titration or discontinuation) because of hyperkalemia at any time during Part B and (2) the proportion of subjects receiving any dose of a RAASi medication at the end of Part B



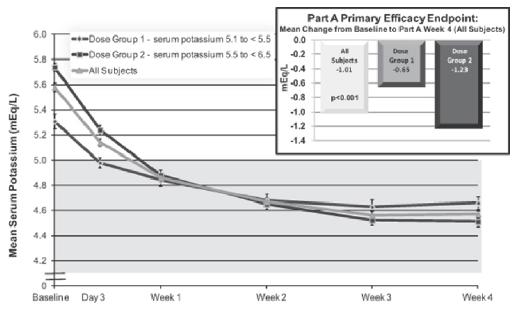


Sources: Company reports and Wedbush Pacgrow Life Sciences

Part A Results: Both the primary and secondary efficacy endpoints were achieved. The change in serum potassium from baseline to week 4 was a reduction of 1.01 mEq/L (p < 0.001; 95% CI -1.07, -0.95). Broken down by dose group, the reduction was 0.65 mEq/L (p < 0.05; 95% CI -0.74, -0.55) and 1.23 mEq/L (p < 0.05; 95% CI -1.31, -1.16) in Dose Group 1 and Dose Group 2, respectively. The proportion of subjects with serum potassium in the target range of 3.8 to < 5.1 mEq/L (normal range) at week 4 (secondary endpoint) was 76% (p < 0.05; 95 CI 70, 81). Adverse events (AE) were reported by 44% of subjects with the most common being mild-to-moderate gastrointestinal (GI) symptoms (19%). Importantly, there were no severe GI events, and thus, we view patiromer's tolerability profile as favorable. There were four serious adverse events (SAEs) and all four were independently assessed as unrelated to patiromer. The four events were paroxysmal atrial fibrillation with tachyarrhythmia, a urinary tract infection with bacteremia and subtherapeutic anticoagulant blood levels, and in the same subject, after study discontinuation, endocarditis, and worsening renal function. Although mean serum magnesium levels remained in the normal range, 3% of subjects developed hypomagnesium with the lowest reported level being 1.2 mg/dL (classified as Grade 1). Although hypomagnesium is a theoretical safety concern for patiromer, we don't believe these data are alarming.



FIGURE 3: PHASE 3 PART A RESULTS



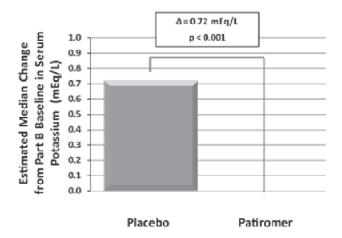
Sources: Company reports and Wedbush Pacgrow Life Sciences

Part B Results: Both the primary and secondary efficacy endpoints were achieved. The difference between the placebo and patiromer groups in the median change in serum potassium from Part B baseline was 0.72 mEq/L (p < 0.001; 95% CI 0.46, 0.97). The two secondary endpoints which evaluated the proportion of subjects who developed recurrent hyperkalemia after having been controlled in patiromer in Part A were also successful. When recurrent hyperkalemia was defined as serum potassium ≥ 5.1 mEq/L, there was a 48% difference between groups in the proportion of patients (43% patiromer vs. 91% placebo) who developed recurrent hyperkalemia (p < 0.001; 95% CI 0.33, 0.63). When recurrent hyperkalemia was defined as serum potassium ≥ 5.5 mEq/L, there was a 45% difference between groups in the proportion of patients (15% patiromer vs. 60% placebo) who developed recurrent hyperkalemia (p < 0.001; 95% CI 0.33, 0.63). In addition, more patients in the placebo group developed recurrent hyperkalemia, and this occurred earlier and more rapidly compared to the patiromer group. Results showed that significantly more placebo patients required dose modification of their RAASi therapies (62%) than patiromer patients (6%), p < 0.001; with more patiromer patients (94%) still on RAASi medication at the end of the trial than placebo patients (48%), p < 0.001. A similar proportion of placebo (46%) and patiromer (46%) subjects reported at least one AE with a greater portion of patiromer subjects (13% patiromer vs. 6% placebo) reporting a GI AE. Importantly, there were no serious GI AEs reported by patiromer subjects. There was one SAE (fatal mesenteric artery and gallbladder artery thrombosis), but it was deemed unrelated to patiromer. Although mean serum magnesium levels remained in the normal range throughout Part B, 2% of subjects in each group developed hypomagnesemia, with no severe cases of hypomagneseia reported.

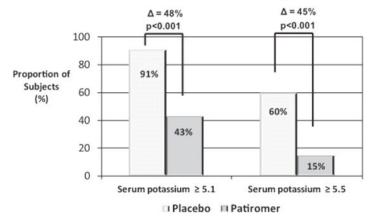


FIGURE 4: PHASE 3 PART B RESULTS

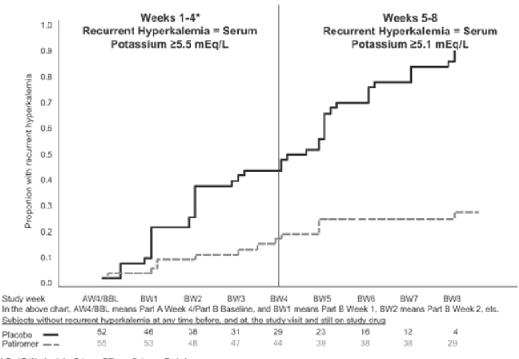
Part B Primary Efficacy Endpoint:
Difference Between Groups in the Median Change in Serum Potassiur
from Part B Baseline to Part B Week 4



Part B Secondary Endpoints: Proportion of Subjects with Recurrent Hyperkalemia at any Time During Part B



Time to First Recurrent Hyperkalemia Event during Part B



^{*} Part B Weeks 1-4 = Primary Efficacy Outcome Period

Sources: Company reports and Wedbush Pacgrow Life Sciences



We reiterate our OUTPERFORM rating and are rolling over to a 12-month price target of \$46 from our previous present day fair value of \$34. By rolling our previous \$34 fair value forward by one year at a 30% annual discount rate, we arrive at our 12-month price target of \$46. 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.

Figure 5: PIPELINE 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	\$6,120	\$1,043,766	\$1,043,766	15%	7	11/4/2015	30%	\$1,231,536	\$35.22
Patiromer (US)	Hyperkalemia (mild / suboptimal RAASi)	13,760,000	\$6,120	\$419,159	\$419,159	2%	7	11/4/2015	30%	\$380,434	\$10.88
Patiromer (EU)	Hyperkalemia (moderate to severe)	2,526,667	\$4,896	\$402,043	\$80,409	10%	7	11/3/2016	30%	\$56,138	\$1.61
Patiromer (EU)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	\$4,896	\$161,454	\$32,291	1%	7	11/3/2016	30%	\$17,342	\$0.50
Patiromer (ROW)	Hyperkalemia (moderate to severe)	2,526,667	\$3,917	\$222,670	\$22,267	8%	7	11/3/2017	30%	\$11,958	\$0.34
Patiromer (ROW)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	\$3,917	\$89,421	\$8,942	1%	7	11/3/2017	30%	\$3,694	\$0.11
RLY-6002	T2D	139,900,146	\$1,446	\$1,154,672	\$540,678	1%	1	1/2/2024	30%	\$10,693	\$0.31
We use multiples to account for clinic	cal and regulatory risk at										
various stages of deve	various stages of development.							<u>Stock</u>	MktCap		Upside
1: in preclinical testing 6: in Phase 3					12-r	nonth Pric	e Target	\$46.10	\$1,611,970		33%
2: passed preclinical	7: Phase 3 data				Total Pipeline Value		\$48.95	\$1,711,796			
3: IND filing/stable mature product	stable mature product 8: regulatory review Cu		urrent Cash	\$2.11	\$73,848						
4: Phase 1 data	9: approved					Curr	ent Price	\$34.60	\$987,359		
5: Phase 2 data	10: launched										

Source: Company data, Wedbush Securities, Inc.

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 Q3:13 with about \$16.5 million in cash, investments, and equivalents. With net proceeds of approximately \$77.9 million from the initial public offering (IPO), we project cash runway through Q1:15. Therefore, Relypsa will likely need to raise additional funds in order to commercially launch patiromer and to ultimately reach profitability, which we model to occur in 2018.



FIGURE 6: MODEL—WE PROJECT FULL-YEAR PROFITABILITY IN 2018

Relypsa, Inc. (RLYP:NASDAQ)							V	/ed	bush Sec		
Historical and Projected Income Statement									Liana M	lous	satos, PhD
(In thousands except per share data)										R	Richard Lau
	2012A		2013E		2014E	2015E	2016E		2017E		2018E
	FY:12A		FY:13E		FY:14E	FY:15E	FY:16E		FY:17E		FY:18E
Revenues:											
Patiromer	-	_	-	_	-	6,506	81,088		237,994	_	565,023
Total Net Product Revenues	\$ -	\$	-	\$	-	\$ 6,506	\$ 81,088	\$	237,994	\$	565,023
Grant Revenue	-		-		-	-	-		-		-
Collaborative Licensing and Development Revenue	-		-		-	-	-		-		-
Total Revenues	\$ -	\$	-	\$	•	\$ 6,506	\$ 81,088	\$	237,994	\$	565,023
Total COGS	-		-		-	5,205	57,915		141,711		270,048
Gross Margin	\$ -	\$	-	\$	-	\$ 1,301	\$ 23,173	\$	96,283	\$	294,975
Operating Expenses:											
R&D	36,052		62,889		28,607	19,375	20,972		22,701		24,601
SG&A	7,285		12,226		18,477	44,499	63,699		66,285		68,977
Acquired in-process R&D	· -		-		-	-	-		-		-
Total Operating Expenses	\$ 43,337	\$	75,115	\$	47,085	\$ 63,874	\$ 84,671	\$	88,987	\$	93,578
Operating Income (Loss)	(43,337)		(75,115)		(47,085)	(62,573)	(61,498)		7,296		201,397
Interest Income / (Expense), net	(382)	,	(15,069)	-	(1,042)	(607)	(340)		(396)		(245)
Other Income / (Expense), net	(6)		(1,395)		(1,453)	(1,459)	(1,460)		(1,460)		(1,459)
Income Before Income Taxes	\$ (43,725)	\$	(91,578)	\$	(49,580)	\$ (64,639)	\$ (63,298)	\$	5,440	\$	199,693
(Provision)/benefit for Income Taxes	_		-		-	-	-		(889)	-	(55,355)
TaxRate	0.0%		0.0%		0.0%	0.0%	0.0%		2.5%		22.0%
Net Income (Loss)	\$ (43,725)	\$	(91,578)	\$	(49,580)	\$ (64,639)	\$ (63,298)	\$	4,551	\$	144,338
GAAP EPS	\$ (8.36)	\$	(10.76)	\$	(1.65)	\$ (2.11)	\$ (2.03)	\$	0.14	\$	4.44
Weighted Average Shares Outstanding	5,228		14,028		30,067	30,667	31,267		31,867		32,467
Cash	\$54,355		\$73,848		\$25,222	(\$57,672)	(\$151,136)		(\$162,227)		(\$34,064)
Cash Per Share			\$5.26		\$0.84	(\$1.88)	(\$4.83)		(\$5.09)		(\$1.05)
Net Cash	\$54,355	_	29,714	_	(18,912)	\$ (101,806)	(195,270)		(206,361)	\$	(78,198)
Net Cash Per Share	\$10.40	-	\$2.12		(\$0.63)	(\$3.32)	(\$6.25)		(\$6.48)		(\$2.41)
Cash Burn (Generation)			\$17,307		\$85,426	\$119,694	\$130,264		\$47,891		(\$91,363)

Sources: Company reports and Wedbush Pacgrow Life Sciences



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., Richard Lau, CFA, 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 <a href="http://www.wedbush.com/ResearchDisclosure/Disclo

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 December 31, 2013)	Investment Banking Relationships (as of December 31, 2013)
Outperform:54%	Outperform:18%
Neutral: 43%	Neutral: 2%
Underperform: 3%	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 January 21, 2014

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

Research Disclosure Legend

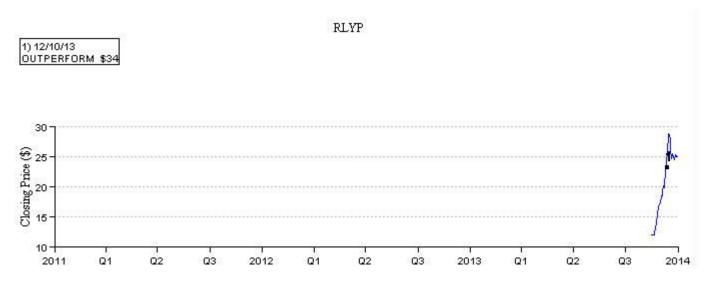
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- 2. WS managed a public offering of securities within the last 12 months.
- 3. WS co-managed a public offering of securities within the last 12 months.
- 4. WS has received compensation for investment banking services within the last 12 months.
- 5. WS provided investment banking services within the last 12 months.
- 6. WS is acting as financial advisor.
- 7. WS expects to receive compensation for investment banking services within the next 3 months.
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Healthy Lifestyles

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Clean Technology

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Environmental Services / Building Products

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Internet: Media and Gaming

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Media

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Medical Diagnostics and Life Sciences Tools

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