Relypsa (RLYP)

Q3 Financials In-Line; Next: FDA Acceptance of Patiromer NDA Submission by Year-End. Reiterate OUTPERFORM and $57 PT.

- **Q3 financials were uneventful.** Relypsa reported no revenues and a net loss of $(0.57) for Q3 versus our $(0.62). R&D expenses were $11.6MM–in-line with our $11.3MM. General and administrative expenses for Q3 were $7.3MM—lower than our $9.2MM. Relypsa ended Q3 2014 with about $143.8MM in cash. We have adjusted our model based on Q3 financials and we project runway into Q4 2015.
- **We anticipate some upside with FDA acceptance of the patiromer NDA submission.** On October 22 2014, Relypsa announced the submission of a new drug application (NDA) to the FDA for US commercialization of patiromer. The FDA has 60 days to respond to the NDA submission, suggesting to us that potential FDA acceptance could occur by year-end. FDA acceptance of patiromer's NDA submission reduces regulatory risk, in our view, and we believe investors are likely to value this anticipated announcement as a PDUFA deadline is expected with it. With highly positive clinical results, supporting the NDA we anticipate FDA approval around Q4 2015 is highly likely. With regulatory and commercial success, we project gross peak annual U.S. sales for patiromer could reach about $1.4 billion.
- **Data that will be presented at American Society of Nephrology Meeting (ASN Nov. 11-16, 2014 Philadelphia) suggests to us that patiromer-treated CKD patients do not experience the first night potassium rebound seen in ZS-9's (ZSPH) Phase I study.** We compared results from patiromer's open label study (SA-PO153) that will be presented at ASN to ZS-9's Phase 2 data presented at American College of Cardiology 2014. Despite only having a twice-daily dosing schedule, patiromer-treated patients did not show a first night rebound in serum potassium levels which was observed in three-times daily treated ZS-9 patients.
- **We reiterate our OUTPERFORM rating and our 12-month price target of $57.** 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.

November 11, 2014

Price
$19.07

Rating
OUTPERFORM

12-Month Price Target
$57

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Company Information	
Shares Outst (M)	34.2
Market Cap (M)	$652
52-Wk Range	$11.90 - $52.74
Book Value/sh	$3.68
Cash/sh	$4.09
Enterprise Value (M)	$776
LT Debt/Cap %	10

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.

FYE Dec	2013A	2014E			2015E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$0.0A	$0.0A			$0.0E		$0.0E
Q2 Jun	0.0A	0.0A			0.0E		0.0E
Q3 Sep	0.0A	0.0A		0.0E	0.0E		0.0E
Q4 Dec	0.0A	0.0E		0.0E	2.9E	6.5E	5.8E
Year*	**$0.0A**	**$0.0E**		**$0.0E**	**$2.9E**	**$6.5E**	**$8.2E**
Change	--	--			--		
	2013A	**2014E**			**2015E**		
EPS	**ACTUAL**	**CURR.**	**PREV.**	**CONS.**	**CURR.**	**PREV.**	**CONS.**
Q1 Mar	$(4.92)A	$(0.54)A			$(0.78)E		($0.70)E
Q2 Jun	(3.78)A	(0.51)A			(0.79)E		(0.73)E
Q3 Sep	(1.30)A	(0.57)A	(0.62)E	(0.63)E	(0.79)E		(0.78)E
Q4 Dec	(0.68)A	(0.77)E		(0.75)E	(0.78)E	(0.76)E	(0.78)E
Year*	**($22.42)A**	**($2.40)E**	**($2.45)E**	**($2.45)E**	**$(3.15)E**	**$(3.13)E**	**($3.02)E**
P/E	--	--			--		
Change	--	--			--		

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

Source: Thomson Reuters

Wedbush Securities does and seeks to do business with companies covered in its research reports. Thus, investors should be aware that the firm may have a conflict of interest that could affect the objectivity of this report. Investors should consider this report as only a single factor in making their investment decision. Please see page 5 of this report for analyst certification and important disclosure information.

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. The company filed the NDA for Patiromer on October 24, 2014, 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: 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	Q2A	Q3A	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	-	-	-	-	-	-	2,928	73,572	219,227	536,223	961,389	1,280,829	1,428,369	1,478,181	1,492,353	1,496,626	1,414,497
Total Net Product Revenues	-	-	-	-	-	-	2,928	73,572	219,227	536,223	961,389	1,280,829	1,428,369	1,478,181	1,492,353	1,496,626	1,414,497
Grant Revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Collaborative Licensing and Development Revenue	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Revenues	$ -	$ -	$ -	$ -	$ -	$ -	$ 2,928	$ 73,572	$ 219,227	$ 536,223	$ 961,389	$ 1,280,829	$ 1,428,369	$ 1,478,181	$ 1,492,353	$ 1,496,626	$ 1,414,497
Total COGS	-	-	-	-	-	-	2,342	52,541	130,495	256,106	346,811	311,335	285,674	295,636	298,471	299,325	282,899
Gross Margin	$ -	$ -	$ -	$ -	$ -	$ -	$ 586	$ 21,030	$ 88,732	$ 280,118	$ 614,579	$ 969,494	$ 1,142,696	$ 1,182,545	$ 1,193,882	$ 1,197,301	$ 1,131,598
Operating Expenses:																	
R&D	58,971	10,909	11,075	11,647	11,522	45,153	48,441	52,434	56,756	61,435	66,499	71,980	77,914	84,337	91,289	98,814	106,959
SG&A	11,940	4,795	5,322	7,311	14,343	31,771	58,820	61,208	63,693	66,279	78,045	102,466	114,270	118,255	119,388	119,730	113,160
Acquired in-process R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	$ 70,911	$ 15,704	$ 16,397	$ 18,958	$ 25,865	$ 76,924	$ 107,260	$ 113,642	$ 120,449	$ 127,714	$ 144,544	$ 174,447	$ 192,183	$ 202,591	$ 210,677	$ 218,544	$ 220,119
Operating Income (Loss)	(70,911)	(15,704)	(16,397)	(18,958)	(25,865)	(76,924)	(106,675)	(92,611)	(31,717)	152,404	470,035	795,048	950,512	979,954	983,205	978,757	911,479
Interest Income / (Expense), net	(1,481)	27	36	17	(159)	(79)	(449)	(261)	(403)	(342)	105	1,017	2,349	3,820	5,321	6,823	8,316
Other Income / (Expense), net	(1,453)	(391)	(376)	(494)	(417)	(1,678)	(1,711)	(1,717)	(1,717)	(1,717)	(1,717)	(1,717)	(1,717)	(1,717)	(1,717)	(1,717)	(1,717)
Income Before Income Taxes	$ (73,845)	$ (16,068)	$ (16,737)	$ (19,435)	$ (26,441)	$ (78,681)	$ (108,835)	$ (94,589)	$ (33,837)	$ 150,345	$ 468,422	$ 794,348	$ 951,144	$ 982,057	$ 986,809	$ 983,863	$ 918,077
Deemed Dividend to preferred stockholders	(7,336)	-	-	-	-	-	-	-	(142)	(29,483)	(182,685)	(309,796)	(370,946)	(383,002)	(384,855)	(383,707)	(358,050)
(Provision)/benefit for Income Taxes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
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)	$ (16,737)	$ (19,435)	$ (26,441)	$ (78,681)	$ (108,835)	$ (94,589)	$ (33,979)	$ 120,861	$ 285,738	$ 484,552	$ 580,198	$ 599,055	$ 601,953	$ 600,157	$ 560,027
Stock-based compensation		1,998	2,065	2,233	1,875	8,171	8,154	8,137	8,132	8,131	8,131	8,131	8,131	8,131	8,131	8,131	8,131
EPS	$ (22.42)	$ (0.61)	$ (0.57)	$ (0.64)	$ (0.83)	$ (2.65)	$ (3.38)	$ (2.92)	$ (1.18)	$ 3.10	$ 7.51	$ 12.68	$ 14.98	$ 15.24	$ 15.08	$ 14.81	$ 13.60
GAAP EPS	$ (22.42)	$ (0.54)	$ (0.51)	$ (0.57)	$ (0.77)	$ (2.40)	$ (3.15)	$ (2.69)	$ (0.95)	$ 3.32	$ 7.73	$ 12.89	$ 15.19	$ 15.45	$ 15.28	$ 15.01	$ 13.80
Weighted Average Shares Outstanding	3,620	29,710	33,141	34,065	34,210	32,782	34,585	35,185	35,785	36,385	36,985	37,585	38,185	38,785	39,385	39,985	40,585
Cash	$94,759	$78,917	$160,393	$139,381	$112,708	$112,708	($9,867)	($134,834)	($183,836)	($80,008)	$189,077	$656,613	$1,230,217	$1,828,470	$2,430,030	$3,030,210	$3,613,234
Cash Per Share	$26.17	$2.66	$4.84	$4.09	$3.29	$3.44	($0.29)	($3.83)	($5.14)	($2.20)	$5.11	$17.47	$32.22	$47.14	$61.70	$75.78	$89.03
Net Cash	$ 84,418	$ 65,975	$144,834	$123,707	$99,420	$ 106,331	$ (16,244)	$ (141,211)	$ (190,213)	$ (86,385)	$ 182,700	$ 650,236	$ 1,223,840	$ 1,822,093	$ 2,423,653	$ 3,023,833	$ 3,606,857
Net Cash Per Share	$23.32	$2.22	$4.37	$3.63	$2.91	$3.24	($0.47)	($4.01)	($5.32)	($2.37)	$4.94	$17.30	$32.05	$46.98	$61.54	$75.62	$88.87
Cash Burn (Generation)	($3,604)					$18,851	$159,374	$161,768	$85,802	($67,028)	($232,285)	($430,736)	($536,805)	($561,453)	($564,760)	($563,379)	($546,224)

Source: Company data, Wedbush Securities, Inc.

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Figure 2: Milestones (*our estimates)

Timing	Milestone	Estimated Probability	Estimated Upside / Downside
Q4:14	Patiromer NDA Acceptance by FDA	80:20	±0-20%
Q2:15*	Potential FDA Advisory Committee Meeting for Patiromer (If necessary)	50:50	±0-20%
Q3:15	Potential FDA Approval of Patiromer	90:10	±0-40%
Q4:15*	Potential US Launch of Patiromer	90:10	±0-10%
2014/2015	Potential Patiromer Partnership(s)	50:50	±0-20%

Source: Company data, Wedbush Securities, Inc.

Data that will be presented at American Society of Nephrology Meeting (ASN Nov. 11-16, 2014 Philadelphia) suggest patiromer-treated patients do not experience the first night potassium rebound seen in ZS-9's (ZSPH) Phase I study. We compared results from patiromer's open label study (SA-PO153) that will be presented at ASN to ZS-9's Phase 2 data presented at American College of Cardiology 2014. Despite only having a twice-daily dosing schedule, patiromer-treated patients did not show a first night rebound in serum potassium levels, which was not observed in three time daily treated ZS-9 patients.

Figure 3: Comparison of Onset and Duration of Action Data between Patiromer and ZS-9

	Patiromer (Relypsa)	ZS-9 (ZS-Pharma)
Poster Title	"Patiromer Induced a Rapid Onset of Action and Sustained K+ Lowering throughout the Dosing Period in CKD Patients with Hyperkalemia" ASN 2014 SA-PO153	"ZS-9, a Novel Selective Cation Trap, Leads to a Rapid and Predictable Rate of Decline in Serum Potassium in Patients With Chronic Kidney Disease and Hyperkalemia" ACC 2014 1180-90
Study Type	Open label, single arm	Double blind, placebo controlled
Dosing Regimen	BID (8am and 6pm)	TID (8am, 12pm and 6pm)
Patient Profile	• CKD • mean baseline serum K+ 5.93 mEq/L	• CKD • mean baseline serum K+ 5.1 mEq/L
Number of Patients	Patiromer 8.4g (n= 25)	ZS-9 10g (n=24) ; placebo (n=30)
Dosing Regimen	BID (8am and 6pm)	TID (8am, 12pm and 6pm)
Onset of Action	• A statistically significant reduction (not statistically significant at 4 hours-first measured time point) compared to baseline in serum K+ observed at all time points tested in a 48 hour period.	• A statistically significant reduction compared to placebo in serum K+ observed only at 1 hour and 14 hours post initiation of ZS-9 (10g). • A reduction (not statistically significant) in serum K+ observed at 0.5, 2, 4 and 8 hours after initiation of drug.
Duration of Action	No rebound in serum K+ observed overnight	Rebound in serum K+ observed overnight (between the 14 and 24 hour time point)
Change in serum K+ at 48 hours after initiation of treatment	-0.75 mEq/L p <0.001	-0.68 mEq/L p <0.0001 (-0.73 75 mEq/L p <0.0001 observed in ZS003 trial)

Source: Company data, Wedbush Securities, Inc.

Figure 4: 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	12/15/2015	30%	$1,506,178	$44.03
Patiromer (US)	Hyperkalemia (mild / suboptimal RAASi)	13,760,000	$6,120	$419,159	$419,159	2%	7	12/15/2015	30%	$447,901	$13.09
Patiromer (EU)	Hyperkalemia (moderate to severe)	2,526,667	$5,059	$417,637	$83,527	10%	7	12/14/2016	30%	$69,947	$2.04
Patiromer (EU)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	$4,896	$161,454	$32,291	1%	7	12/14/2016	30%	$20,800	$0.61
Patiromer (ROW)	Hyperkalemia (moderate to severe)	2,526,667	$4,047	$231,307	$23,131	8%	7	12/14/2017	30%	$14,900	$0.44
Patiromer (ROW)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	$3,917	$89,421	$8,942	1%	7	12/14/2017	30%	$4,431	$0.13
RLY-6002	T2D	139,900,146	$1,446	$1,154,672	$540,678	1%	1	12/15/2015	30%	$109,311	$3.20
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			$57.12	$1,954,079		200%
2: passed preclinical	7: Phase 3 data					Total Pipeline Value		$63.53	$2,173,468		
3: IND filing/stable mature product	8: regulatory review					Current Cash		$4.07	$139,381		
4: Phase 1 data	9: approved					Current Price		$19.07	$651,039		
5: Phase 2 data	10: launched										

Source: Company data, Wedbush Securities, Inc.

We reiterate our OUTPERFORM rating and our 12-month price target of $57. 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 THE ATTAINMENT OF OUR 12-MONTH PRICE TARGET

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 2014 with about $143.8MM 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/DisclosureQ314.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 September 30, 2014)	**Investment Banking Relationships (as of September 30, 2014)**
Outperform:54% Neutral: 43% Underperform: 3%	Outperform:23% Neutral: 1% 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 November 11, 2014

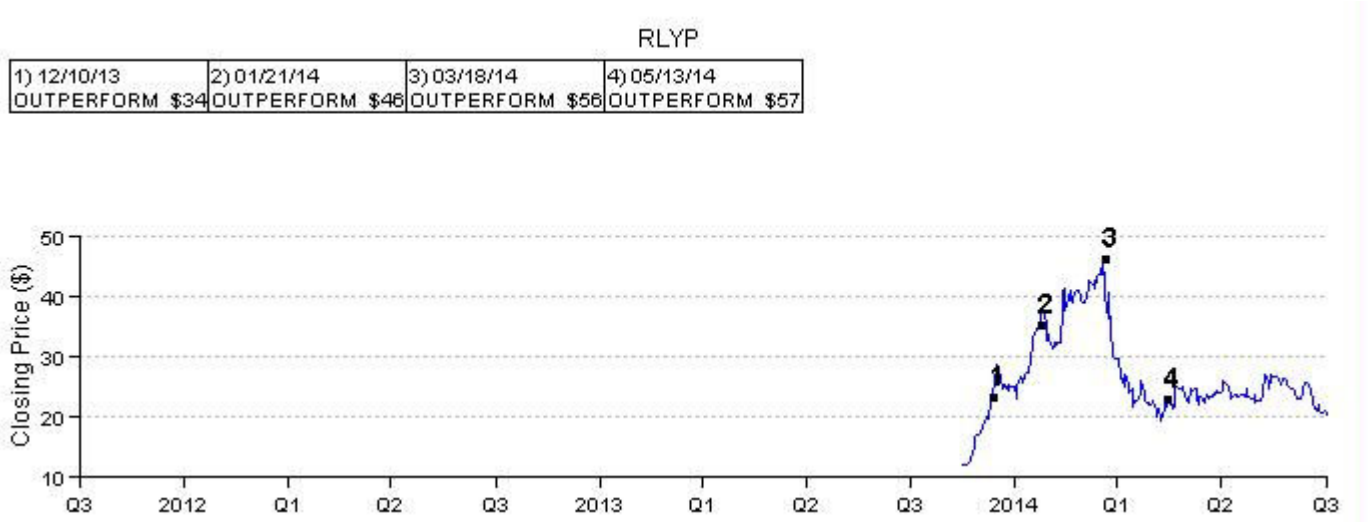
Company	Disclosure
Relypsa	1,3,4,5

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.
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.
8. WS provided non-investment banking securities-related services within the past 12 months.
9. WS has received compensation for products and services other than investment banking services within the past 12 months.

10. The research analyst, a member of the research analyst's household, any associate of the research analyst, or any individual directly involved in the preparation of this report has a long position in the common stocks.
11. WS or one of its affiliates beneficially own 1% or more of the common equity securities.
12. The analyst maintains Contingent Value Rights that enables him/her to receive payments of cash upon the company's meeting certain clinical and regulatory milestones.

Price Charts

Wedbush disclosure price charts are updated within the first fifteen days of each new calendar quarter per FINRA regulations. Price charts for companies initiated upon in the current quarter, and rating and target price changes occurring in the current quarter, will not be displayed until the following quarter. Additional information on recommended securities is available on request.



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