Relypsa (RLYP)

2013 Financials in Line, Except One-Time Expense; We Continue to Anticipate Regulatory Progress In 2014; Reiterate OUTPERFORM and Increase PT to $56

- **2013 financials were in line, except for a deemed dividend and lower-than-expected share count.** Relypsa reported no revenues, as expected, and a loss of $(0.68) for Q4 and $(22.42) for FY versus our $(0.78)/$(10.76), respectively. Although revenues and operating expenses were in line, the company reported a deemed dividend to preferred stockholders of $(7.3) million in Q4, which we did not include, and a share count of 13.4 million in Q4 (3.6 million for FY2013) versus our 25.75 million (14 million) estimates, respectively. Relypsa ended 2013 with about $94.8 million in cash and we project runway into 2015. 2014 guidance for operation expenses of $75-$95 million and $5-$10 million for stock-based compensation as well as 2013 financial results have been incorporated into our model.
- **We believe Relypsa is on track to file an NDA for patiromer in Q3 2014.** 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. 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 increase our 12-month price target to $56 due to share count adjustment.** We have adjusted our diluted share count to just under 30 million—in line with the 29.7 million reported at the end of 2013. Although our market capitalization calculation of about $1.68 billion remains the same, the lower share count increased our PT to $56 from $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 followed by a 365-day projection for time value.

March 18, 2014

Price
$43.91

Rating
OUTPERFORM

12-Month Price Target
$56 **(from $46)**

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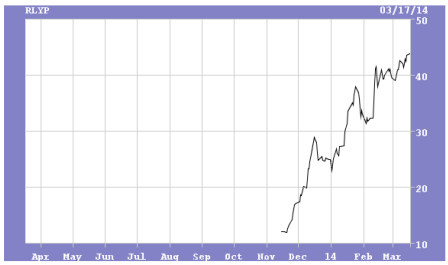
Company Information	
Shares Outst (M)	28.7
Market Cap (M)	$1261
52-Wk Range	$11.90 - $46.81
Book Value/sh	$5.57
Cash/sh	$7.06
Enterprise Value (M)	$1343
LT Debt/Cap %	6

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	2012A	2013E			2014E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	$0.0A		N/AA	$0.0E		$0.0E
Q2 Jun	--	0.0A		N/AA	0.0E		0.0E
Q3 Sep	--	0.0A		N/AA	0.0E		0.0E
Q4 Dec	--	0.0E		0.0E	0.0E		0.0E
Year*	**$0.0A**	**$0.0E**		**$0.0E**	**$0.0E**		**$0.0E**
Change	--	--			--		
	2012A	2013E			2014E		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	--	$(4.92)A		N/AA	$(0.54)E	$(0.53)E	($0.52)E
Q2 Jun	--	(3.78)A		N/AA	(0.64)E	(0.44)E	(0.53)E
Q3 Sep	--	(1.30)A		N/AA	(0.77)E	(0.31)E	(0.54)E
Q4 Dec	--	(0.68)E	(0.76)E	(0.59)E	(0.95)E	(0.38)E	(0.57)E
Year*	**$(8.36)A**	**($22.42)E**	**($10.76)E**	**($3.41)E**	**($2.91)E**	**($1.65)E**	**($2.18)E**
P/E	--	--			--		
Change	--	--			--		

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



Source: Thomson Reuters

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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 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.

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)

	2012A	2013A					2014E					2015E	2016E	2017E	2018E
	FY:12A	Q1A	Q2A	Q3A	Q4A	FY:13A	Q1E	Q2E	Q3E	Q4E	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	22,604	13,295	12,158	10,914	58,971	11,132	11,355	11,582	11,814	45,883	49,665	53,759	58,191	62,987
SG&A	7,285	2,535	2,988	2,685	3,732	11,940	4,394	7,188	11,135	16,246	38,964	66,627	69,332	72,147	75,077
Acquired in-process R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	$ 43,337	$ 25,139	$ 16,283	$ 14,843	$ 14,646	$ 70,911	$ 15,527	$ 18,543	$ 22,717	$ 28,060	$ 84,847	$ 116,292	$ 123,091	$ 130,338	$ 138,064
Operating Income (Loss)	(43,337)	(25,139)	(16,283)	(14,843)	(14,646)	(70,911)	(15,527)	(18,543)	(22,717)	(28,060)	(84,847)	(114,991)	(99,918)	(34,055)	156,911
Interest Income / (Expense), net	(382)	(864)	(3,549)	(10,382)	13,314	(1,481)	(291)	(264)	(242)	(223)	(1,019)	(723)	(561)	(718)	(655)
Other Income / (Expense), net	(6)	(248)	(388)	(410)	(407)	(1,453)	(363)	(392)	(393)	(389)	(1,537)	(1,551)	(1,553)	(1,553)	(1,553)
Income Before Income Taxes	$ (43,725)	$ (26,251)	$ (20,220)	$ (25,635)	$ (1,739)	$ (73,845)	$ (16,180)	$ (19,199)	$ (23,352)	$ (28,672)	$ (87,403)	$ (117,264)	$ (102,032)	$ (36,326)	$ 154,703
Deemed Dividend to preferred stockholders					(7,336)	(7,336)									
(Provision)/benefit for Income Taxes	-	-	-	-	-	-	-	-	-	-	-	-	-	(148)	(30,166)
Tax Rate	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	1.3%	13.5%
Net Income (Loss)	$ (43,725)	$ (26,251)	$ (20,220)	$ (25,635)	$ (9,075)	$ (81,181)	$ (16,180)	$ (19,199)	$ (23,352)	$ (28,672)	$ (87,403)	$ (117,264)	$ (102,032)	$ (36,474)	$ 124,537
Stock-based compensation							1,875	1,875	1,875	1,875	7,500	7,500	7,500	7,500	7,500
EPS	$ (8.36)	$ (4.92)	$ (3.78)	$ (1.30)	$ (0.49)	$ (22.42)	$ (0.61)	$ (0.70)	$ (0.84)	$ (1.01)	$ (3.16)	$ (4.07)	$ (3.50)	$ (1.38)	$ 3.60
GAAP EPS	$ (8.36)	$ (4.92)	$ (3.78)	$ (1.30)	$ (0.68)	$ (22.42)	$ (0.54)	$ (0.64)	$ (0.77)	$ (0.95)	$ (2.91)	$ (3.82)	$ (3.26)	$ (1.14)	$ 3.84
Weighted Average Shares Outstanding	5,228	5,337	5,349	19,673	13,430	3,620	29,842	29,992	30,142	30,292	30,067	30,667	31,267	31,867	32,467
Cash	$54,355	$43,557	$32,301	$16,467	$94,759	$94,759	$85,077	$64,030	$38,830	$8,310	$8,310	($127,209)	($259,407)	($311,524)	($203,162)
Cash Per Share	-	$8.16	$6.04	$0.84	$7.06	$26.17	$2.85	$2.13	$1.29	$0.27	$0.28	($4.15)	($8.30)	($9.78)	($6.26)
Net Cash	$54,355	$ 31,260	$18,715	$2,836	$82,225	$ 83,911	$ 66,095	$46,946	$23,644	($4,978)	$ (2,538)	$ (138,057)	$ (270,255)	$ (322,372)	$ (214,010)
Net Cash Per Share	$10.40	$5.86	$3.50	$0.14	$6.12	$23.18	$2.21	$1.57	$0.78	($0.16)	($0.08)	($4.50)	($8.64)	($10.12)	($6.59)
Cash Burn (Generation)						($3,604)					$123,249	$172,319	$168,999	$88,916	($71,562)

Source: Company data, Wedbush Securities, Inc.

2013 financials were in line, except deemed dividend and share count. Relypsa reported no revenues, as expected, and a loss of $(0.68) for Q4 and $(22.42) for FY versus our $(0.78)/$(10.76), respectively. Although revenues and operating expenses were in line, the company reported a deemed dividend to preferred stockholders of $(7.3) million in Q4, which we did not include and a share count of 13.4 million in Q4 (3.6 million for FY2013) versus our 25.75 million (14 million) estimates, respectively. Relypsa ended 2013 with

about $94.8 million in cash and we project runway into 2015. 2014 guidance for operation expenses of $75-$95 million and $5-$10 million for stock-based compensation as well as 2013 financial results have been incorporated into our model.

Figure 2: MILESTONES (*our estimates)

H1:14	COMPLETION OF CMC ACTIVITIES SUPPORTIVE OF NDA
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.

We believe Relypsa is on track to file an NDA for patiromer in Q3 2014. 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. With regulatory and commercial success, we project gross peak annual US 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	$6,120	$1,043,766	$1,043,766	15%	7	11/4/2015	30%	$1,282,121	$42.96
Patiromer (US)	Hyperkalemia (mild / suboptimal RAASi)	13,760,000	$6,120	$419,159	$419,159	2%	7	11/4/2015	30%	$396,060	$13.27
Patiromer (EU)	Hyperkalemia (moderate to severe)	2,526,667	$4,896	$402,043	$80,409	10%	7	11/3/2016	30%	$58,444	$1.96
Patiromer (EU)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	$4,896	$161,454	$32,291	1%	7	11/3/2016	30%	$18,054	$0.60
Patiromer (ROW)	Hyperkalemia (moderate to severe)	2,526,667	$3,917	$222,670	$22,267	8%	7	11/3/2017	30%	$12,450	$0.42
Patiromer (ROW)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	$3,917	$89,421	$8,942	1%	7	11/3/2017	30%	$3,846	$0.13
RLY-6002	T2D	139,900,146	$1,446	$1,154,672	$540,678	1%	1	1/2/2024	30%	$11,132	$0.37
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			$56.23	$1,678,181		28%
2: passed preclinical	7: Phase 3 data					Total Pipeline Value		$59.72	$1,782,107		
3: IND filing/stable mature product	8: regulatory review					Current Cash		$3.18	$94,759		
4: Phase 1 data	9: approved					Current Price		$43.91	$1,258,671		
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 $56 due to share count adjustment. We have adjusted our diluted share count to just under 30 million—in line with the 29.7 million reported at the end of 2013. Although our market capitalization calculation of about $1.68 billion remains the same, the lower share count increased our PT to $56 from $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 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 2013 with about $94.8 million in cash and we project runway into 2015. Therefore, we believe 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.

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/DisclosureQ413.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.
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Rating Distribution (as of December 31, 2013)	**Investment Banking Relationships (as of December 31, 2013)**
Outperform:54% Neutral: 43% Underperform: 3%	Outperform:18% Neutral: 2% Underperform: 0%

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

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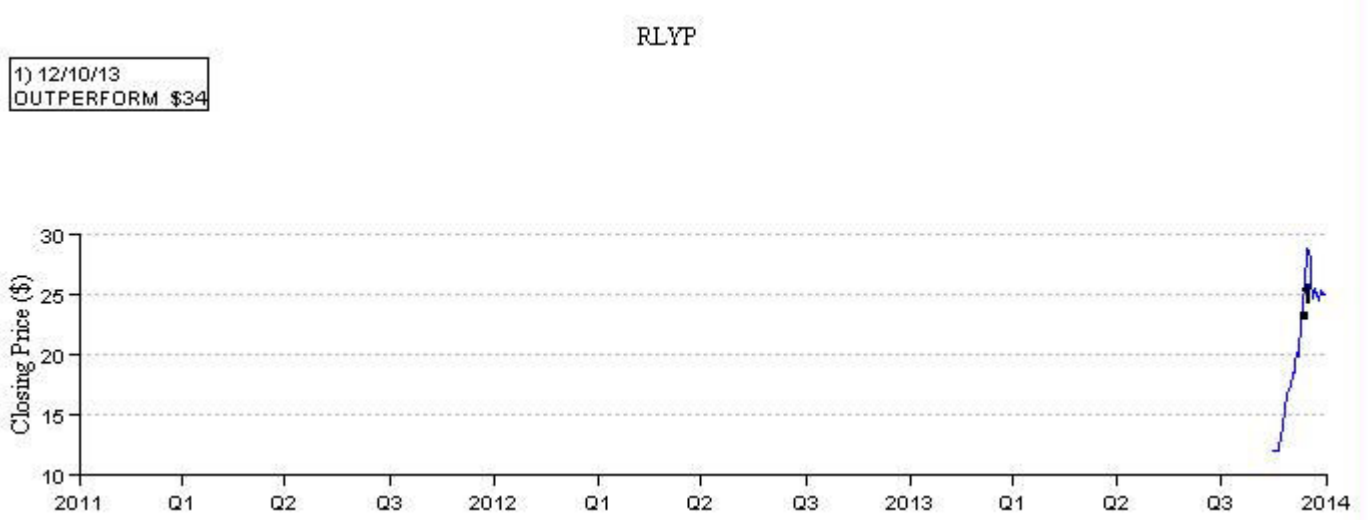

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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