Relypsa (RLYP)

Corporate Update: Financing Supports Patiromer Regulatory and Potential Commercial Progress; Reiterate OUTPERFORM and $56 PT

- **Relypsa conducted a follow-on financing, raising approximately $94.8MM net (with shoe/$82.5MM w/o shoe), which we project extends runway to potential patiromer launch in Q4 2015.** The company sold approximately 3,591,836 shares at $24.50/share and with a 15% green shoe (538,775 shares) and we estimate the total net raise after fees to be about $94.8MM. With the approximate $95MM in year-end 2014 cash and this follow-on offering, the cash runway should cover patiromer's clinical, regulatory, and pre-commercial progress. However, we estimate that the company will need to conduct another financing prior to launch unless they pursue a strategic commercial partner for primary care and potentially ex-US commercialization. The company plans to build a 100-person sales force in the US to cover the specialists (nephrologists and cardiologists). We have incorporated the additional share count and net cash raised into our model. The dilution impacted our EPS (loss) estimates from Q2 2014 on.
- **Management is delivering, in our view.** Although we do not view this as likely to have an impact on RLYP's valuation near-term, we should hear about top-line results from the Phase 1 onset of action trial in Q2. This trial was requested by the FDA to fill out the pharmacokinetic / pharmacodynamic profile of patiromer. The company has kept on track to 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 12-month price target of $56.** 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.

April 11, 2014

Price
$23.56

Rating
OUTPERFORM

12-Month Price Target
$56

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Company Information	
Shares Outst (M)	33.8
Market Cap (M)	$797
52-Wk Range	$11.90 - $52.74
Book Value/sh	$3.97
Cash/sh	$4.69
Enterprise Value (M)	$939
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.

FYE Dec	2013A	2014E			2015E		
REV (M)	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$0.0A	$0.0E		$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**		**$9.8E**
Change	--	--			--		
	2013A	**2014E**			**2015E**		
EPS	ACTUAL	CURR.	PREV.	CONS.	CURR.	PREV.	CONS.
Q1 Mar	$(4.92)A	$(0.54)E		($0.54)E	$(0.85)E	$(0.95)E	N/AE
Q2 Jun	(3.78)A	(0.57)E	(0.64)E	(0.62)E	(0.85)E	(0.96)E	N/AE
Q3 Sep	(1.30)A	(0.69)E	(0.77)E	(0.72)E	(0.86)E	(0.97)E	N/AE
Q4 Dec	(0.68)A	(0.84)E	(0.95)E	(0.82)E	(0.83)E	(0.94)E	N/AE
Year*	**($22.42)A**	**($2.65)E**	**($2.91)E**	**($2.70)E**	**$(3.39)E**	**$(3.82)E**	**($3.06)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)

	2013A	2014E					2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
	FY:13A	Q1E	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	11,132	11,355	11,582	11,814	45,883	49,665	53,759	58,191	62,987	68,180	73,800	79,883	86,468	93,596	101,311	109,663
SG&A	11,940	4,394	7,188	11,135	16,246	38,964	66,627	69,332	72,147	75,077	80,470	104,395	114,996	117,971	118,963	119,261	107,019
Acquired in-process R&D	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Operating Expenses	$ 70,911	$ 15,527	$ 18,543	$ 22,717	$ 28,060	$ 84,847	$ 116,292	$ 123,091	$ 130,338	$ 138,064	$ 148,649	$ 178,195	$ 194,879	$ 204,439	$ 212,559	$ 220,572	$ 216,682
Operating Income (Loss)	(70,911)	(15,527)	(18,543)	(22,717)	(28,060)	(84,847)	(114,991)	(99,186)	(31,050)	165,873	494,039	809,321	955,083	975,267	977,068	972,039	853,511
Interest Income / (Expense), net	(1,481)	(291)	(234)	(182)	(163)	(871)	(486)	(324)	(477)	(401)	82	1,028	2,376	3,851	5,345	6,838	8,313
Other Income / (Expense), net	(1,453)	(363)	(392)	(393)	(389)	(1,537)	(1,551)	(1,553)	(1,553)	(1,553)	(1,553)	(1,553)	(1,553)	(1,553)	(1,553)	(1,553)	(1,553)
Income Before Income Taxes	$ (73,845)	$ (16,181)	$ (19,169)	$ (23,293)	$ (28,612)	$ (87,255)	$ (117,027)	$ (101,063)	$ (33,080)	$ 163,920	$ 492,568	$ 808,796	$ 955,906	$ 977,565	$ 980,859	$ 977,324	$ 860,272
Deemed Dividend to preferred stockholders	(7,336)																
(Provision)/benefit for Income Taxes	-	-	-	-	-	-	-	-	(208)	(31,689)	(192,102)	(315,430)	(372,803)	(381,250)	(382,535)	(381,156)	(335,506)
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)	$ (16,181)	$ (19,169)	$ (23,293)	$ (28,612)	$ (87,255)	$ (117,027)	$ (101,063)	$ (33,288)	$ 132,230	$ 300,467	$ 493,365	$ 583,103	$ 596,315	$ 598,324	$ 596,168	$ 524,766
Stock-based compensation		1,875	1,875	1,875	1,875	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500	7,500
EPS	$ (22.42)	$ (0.61)	$ (0.62)	$ (0.74)	$ (0.89)	$ (2.88)	$ (3.61)	$ (3.09)	$ (1.14)	$ 3.43	$ 7.94	$ 12.95	$ 15.10	$ 15.21	$ 15.03	$ 14.75	$ 12.77
GAAP EPS	$ (22.42)	$ (0.54)	$ (0.57)	$ (0.69)	$ (0.84)	$ (2.65)	$ (3.39)	$ (2.88)	$ (0.93)	$ 3.64	$ 8.14	$ 13.15	$ 15.30	$ 15.40	$ 15.22	$ 14.93	$ 12.95
Weighted Average Shares Outstanding	3,620	29,715	33,845	33,995	34,145	32,925	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	$84,959	$158,776	$133,434	$102,772	$102,772	($32,045)	($164,211)	($213,617)	($98,008)	$187,534	$665,336	$1,242,608	$1,839,882	$2,437,888	$3,034,101	$3,597,302
Cash Per Share	$26.17	$2.86	$4.69	$3.93	$3.01	$3.12	($0.93)	($4.68)	($5.98)	($2.70)	$5.08	$17.73	$32.60	$47.52	$62.00	$76.00	$88.78
Net Cash	$ 84,418	$ 65,977	$141,692	$118,248	$89,484	$ 92,431	$ (42,386)	$ (174,552)	$ (223,958)	$ (108,348)	$ 177,193	$ 654,995	$ 1,232,267	$ 1,829,541	$ 2,427,547	$ 3,023,760	$ 3,586,961
Net Cash Per Share	$23.32	$2.22	$4.19	$3.48	$2.62	$2.81	($1.23)	($4.97)	($6.27)	($2.98)	$4.80	$17.46	$32.33	$47.25	$61.74	$75.74	$88.52
Cash Burn (Generation)	($3,604)					$28,787	$171,617	$168,965	$86,206	($78,809)	($248,742)	($441,002)	($540,472)	($560,474)	($561,206)	($559,413)	($526,401)

Source: Company data, Wedbush Securities, Inc.

Relypsa conducted a follow-on financing, raising approximately $94.8MM net (with shoe/$82.5MM w/o shoe), which we project extends runway to potential patiromer launch in Q4 2015. The company sold approximately 3,591,836 shares at $24.50/share and with a 15% green shoe (538,775 shares) and we estimate the total net raise after fees to be about $94.8MM. With the approximate $95MM in year-end 2014 cash and this follow-on offering, the cash runway should cover patiromer's clinical, regulatory, and pre-commercial progress. However, we estimate that the company will need to conduct another financing prior to launch unless they pursue a strategic commercial partner for primary care and potentially ex-US commercialization. The company plans to build a 100-person sales force in the US to cover the specialists (nephrologists and cardiologists).

We have incorporated the additional share count and net cash raised into our model. The dilution impacted our EPS (loss) estimates from Q2 2014 on.

Figure 2: MILESTONES (*our estimates)

Q2:14	COMPLETION OF CMC ACTIVITIES SUPPORTIVE OF NDA
Q2:14	TOP-LINE PHASE 1 ONSET OF ACTION RESULTS
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 is delivering, in our view. Although we do not view this as likely to have an impact on RLYP's valuation near-term, we should hear about top-line results from the Phase 1 onset of action trial in Q2. This trial was requested by the FDA to fill-out the pharmacokinetic / pharmacodynamic profile of patiromer. The company has kept on track to 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%	$1,449,877	$42.84
Patiromer (US)	Hyperkalemia (mild / suboptimal RAASi)	13,760,000	$6,120	$419,159	$419,159	2%	7	11/4/2015	30%	$431,159	$12.74
Patiromer (EU)	Hyperkalemia (moderate to severe)	2,526,667	$5,059	$417,637	$83,527	10%	7	11/3/2016	30%	$61,768	$1.82
Patiromer (EU)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	$4,896	$161,454	$32,291	1%	7	11/3/2016	30%	$18,368	$0.54
Patiromer (ROW)	Hyperkalemia (moderate to severe)	2,526,667	$4,047	$231,307	$23,131	8%	7	11/3/2017	30%	$13,158	$0.39
Patiromer (ROW)	Hyperkalemia (mild / suboptimal RAASi)	9,173,333	$3,917	$89,421	$8,942	1%	7	11/3/2017	30%	$3,913	$0.12
RLY-6002	T2D	139,900,146	$1,446	$1,154,672	$540,678	1%	1	1/2/2024	30%	$11,326	$0.33
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			$55.58	$1,881,035		136%
2: passed preclinical	7: Phase 3 data					Total Pipeline Value		$58.78	$1,989,567		
3: IND filing/stable mature product	8: regulatory review					Current Cash		$4.69	$158,776		
4: Phase 1 data	9: approved					Current Price		$23.56	$749,702		
5: Phase 2 data	10: launched										

Source: Company data, Wedbush Securities, Inc.

We reiterate our OUTPERFORM rating and 12-month price target of $56. 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 $94.8MM in cash and raised approximately $94.8MM in a follow-on offering on April 10, 2014. 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 April 11, 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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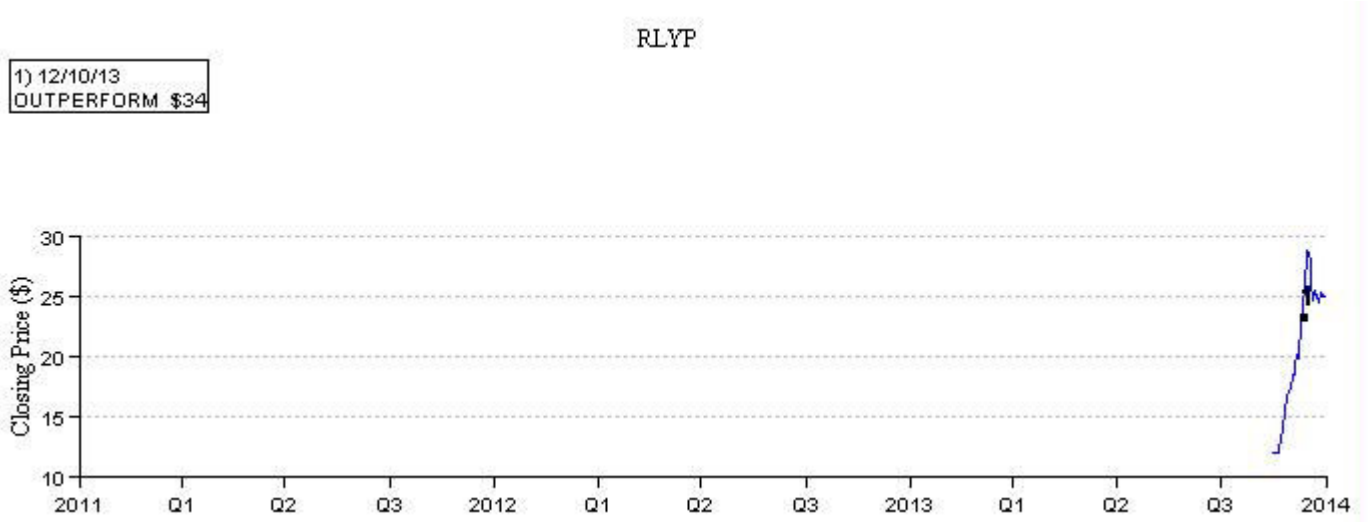

* WS changed its rating system from (Strong Buy/Buy/Hold/Sell) to (Outperform/ Neutral/Underperform) on July 14, 2009.
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