Relypsa

Equity Research

Company Quick Take

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Price: $18.77 (10/21/2014)
Price Target: NA

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: RLYP
Market Cap (MM)	$638.1

Patiromer NDA Submitted

The Cowen Insight

Relypsa announced the submission of its NDA for Patiromer. We view Patiromer as an effective treatment for the long term management of hyperkalemia, and view FDA approval as low risk. We estimate patiromer will be the first to enter this large market, and model sales ramping to nearly $1B over time (~10% market share). We expect RLYP shares to outperform leading into FDA approval.

One Step Closer To Managing Chronic Hyperkalemia

Consistent with its most recent guidance, Relypsa has submitted an NDA for patiromer, brand name Patiromer For Oral Suspension (or Patiromer FOS). Patiromer is likely to be the first new treatment in 50 years for managing hyperkalemia (HK), a life-threatening conditions that is characterized by abnormally high levels of potassium in the blood. The NDA is supported by eight clinical trials that demonstrate Patiromer's efficacy and safety for the chronic treatment of hyperkalemia, which represents the great majority of the hyperkalemia opportunity.

An SPA-sponsored pivotal Phase III trial established that patiromer is effective at reducing serum potassium to normal ranges in ~76% of patients. The trial had a randomized withdrawal phase (Part B) that was undertaken in patients with moderate to high hyperkalemia, (K+ concentration > 5.5 mEq/L) meant to provide additional efficacy evidence and assess the impact of chronic dosing even in this difficult to treat population. The Part B trial met its primary endpoint, with the difference between the patiromer and the placebo groups in the median change in serum potassium levels from the start of Part B to week 4 equal to 0.72 mEq/L. Chronic dosing of patiromer is also supported by a positive Phase IIb trial which evaluated Patiromer FOS in patients for up to one year, the longest prospective study undertaken by a new candidate treatment in the hyperkalemia setting.

Importantly, the Phase III trial also met its exploratory endpoints designed to investigate the ability of patiromer to assist doctors in managing RAASi dosing of patients at risk of hyperkalemia. Due to this heightened hyperkalemia risk, many CKD and heart failure patients receive insufficient doses of the standard RAASi therapies, drugs known to delay disease progression, but also exacerbate HK. Moreover, following the onset-of-action study, it was determined that patiromer reliably reduces serum potassium in moderate to severe hyperkalemia CKD patients as early as 7 hours. This raises the possibility for patiromer to replace Kayexalate in the emergency room setting, as a maintenance medication after patients are administered fast acting but limited-effect drugs (calcium gluconate, insulin, beta-agonist).

Modest Market Share Could Translate Into Big Sales Gains

CKD represents a large and growing patient population driven by rising rates of obesity and diabetes. Physician checks suggest that managing hyperkalemia is a major unmet medical need, and that CKD and HF specialists would be receptive

to a well tolerated treatment that would allow them to optimize RAASi dosing. The hyperkalemia market is wide open, and our assumptions for patiromer's market share are fairly modest. We would expect any subsequent therapeutic to expand the market rather than compete with patiromer for share. Although there are no head-to-head trials comparing Patiromer to the most likely next entrant, ZS Pharma's ZS-9 (NDA submission planed for H1:15), the drugs appear to have roughly equivalent efficacy/ safety profiles, though ZS-9 should benefit from once daily dosing while Patiromer (BID dosing) holds first to market advantage. We note that Relypsa already has data indicating patiromer is as effective in QD as BID, and plans to initiate a study to support once daily approval around YE. We estimate Patiromer FOS will launch in late 2015 and model its U.S. market share growing from 0.6% in 2016 to 5.0% in 2022, with U.S. sales projected to reach $400 by 2020. We expect RLYP shares to outperform as patiromer advances towards its likely FDA approval in 2015.

Valuation Methodology And Risks

Valuation Methodology

Biotechnology:

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

Investment Risks

Biotechnology:

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

Risks To The Price Target

Relypsa has no approved products and its entire future revenue stream depends on the commercial success of patiromer, the company's only product. Patiromer is still in clinical development. Even though it has successfully completed Phase III clinical trials, unexpected safety issues could emerge, thus jeoperdizing the FDA approval process. To produce patiromer, Relypsa relies on a series of third-party manufacturers and depends on these entities to fulfill orders. In addition, patiromer sales may fall short of expectations. The drug treats hyperkalemia, a symptom that is often times induced by the administration of other drugs. The number of patients suffering from this complication may be smaller than expected.

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Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
RLYP	Relypsa

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Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

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Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

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Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

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Distribution of Ratings/Investment Banking Services (IB) as of 09/30/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	440	59.95%	105	23.86%
Hold (b)	278	37.87%	10	3.60%
Sell (c)	16	2.18%	0	0.00%

(a) Corresponds to "Outperform" rated stocks as defined in Cowen and Company, LLC's rating definitions. (b) Corresponds to "Market Perform" as defined in Cowen and Company, LLC's ratings definitions. (c) Corresponds to "Underperform" as defined in Cowen and Company, LLC's ratings definitions.

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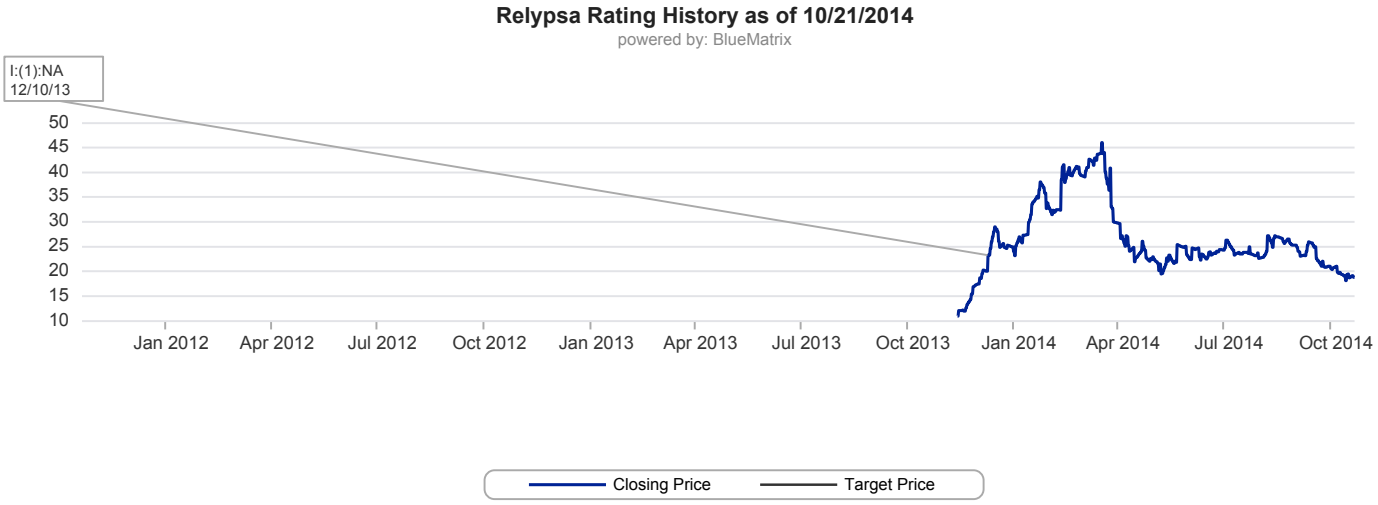

Legend for Price Chart:

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | $xx = Price Target | NA = Not Available | S=Suspended

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