COWEN
AND COMPANY

Biotechnology

Relypsa, Inc

Equity Research

Company Quick Take

January 13, 2014

Price: $27.30 (01/10/2014)
Price Target: NA

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: RLYP
Market Cap (MM)	$810.6

New Data Supports A Clinical Benefit For Patiromer

The Cowen Insight

New Phase III data demonstrate that CKD patients treated with patiromer are more likely to tolerate and maintain therapy with RAASi without dangerous spikes in serum potassium. These results provide evidence of the clinical benefit of patiromer, and should facilitate adoption. We expect RLYP shares to outperform as patiromer advances toward potential FDA approval in 2015.

New Data Suggest Patiromer Can Improve Care For Patients

Relypsa has developed patiromer for the treatment of elevated blood levels of potassium levels known as hyperkalemia (HK). Patients with chronic kidney disease (CKD) and heart failure (HF) represent populations at risk of developing this life-threatening condition. Importantly, due to this heightened hyperkalemia risk, many patients in this category receive insufficient doses of the standard RAASi therapies, drugs known to delay disease progression, but also exacerbate HK. Therefore, a truly successful hyperkalemia drug will not only decrease blood levels of potassium, it will also afford doctors flexibility in dosing RAAS inhibitors when treating CKD and HF patients.

Prior data from an SPA-sponsored pivotal Phase III trial clearly established that patiromer is effective at reducing serum potassium to normal ranges (observed in 76% of patients). Part A of this two-part Phase III study was a single-blind, single-arm trial with a primary endpoint of change from baseline to week 4 in mean serum potassium. Once patients reached steady potassium levels, they were allowed to advance to the Part B of the study, a placebo controlled randomized withdrawal trial, included exploratory endpoints meant to inform on the clinical benefit of using patiromer. Namely, Relypsa sought to determine if at any point during the Part B 8-week period, the proportion of subjects requiring any dose modification of RAASi therapies because of hyperkalemia would differ between patiromer and placebo groups. In addition, the proportion of subjects receiving any dose of a RAASi medication at the end of Part B was to be determined. The protocol specified that if recurrent hyperkalemia developed during Part B, RAASi therapy dose was to be reduced in the placebo group, while patiromer uptitrated in the patiromer group. If these interventions did not normalize serum potassium, the discontinuation of RAASi medication was required, which is common practice in hospitals.

Today, Relypsa released data from these exploratory endpoints, boosting confidence that patiromer can assist doctors in managing RAASi dosing of patients at risk of hyperkalemia. Results show that significantly more placebo patients required dose modification of their RAASi therapies (62%) compared to patiromer patients (6%), $p<0.001$. Moreover, at the end of the trial, 94% of patiromer patients were still on RAASi therapy, as opposed to only 48% of placebo patients $p<0.001$.

Additional Company Updates

Management also reported that the Phase 1 onset-of-action study is on track to provide data in the first half of 2014, and thus an NDA for patiromer is likely to be submitted by Q3:14. In preparation for patiromer launch, Relypsa is acting on its promise to contract additional manufacturers. The company signed a multi-year manufacturing and supply agreement with Lanxess Corporation. The contract names Saltigo, a Lanxess affiliate and leading supplier in the field of polymer synthesis, as the third-party responsible to produce the active pharmaceutical ingredient (API) for patiromer and support Relypsa in preparing and filing its NDA.

Our Take On The News

We view today's data on RAASi utilization in hyperkalemic patients undergoing patiromer treatment as boding well for the adoption of patiromer by nephrologists and cardiologists. The addressable U.S. market opportunity is large, with over 2M moderate to severe hyperkalemia patients presenting to specialist physicians. We model sales ramping to nearly $1B over time assuming fairly modest market penetration estimates (~10% market share). We expect RLYP shares to outperform as patiromer advances toward potential 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

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
RLYP	Relypsa, Inc

Analyst Certification

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Cowen and Company, LLC and/or its affiliates expect to receive, or intend to seek, compensation for investment banking services in the next 3 months from Relypsa, Inc.

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

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

Underperform (3): Stock expected to underperform the S&P 500

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

Cowen Securities, formerly known as Dahlman Rose & Company, Rating System until May 25, 2013

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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Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

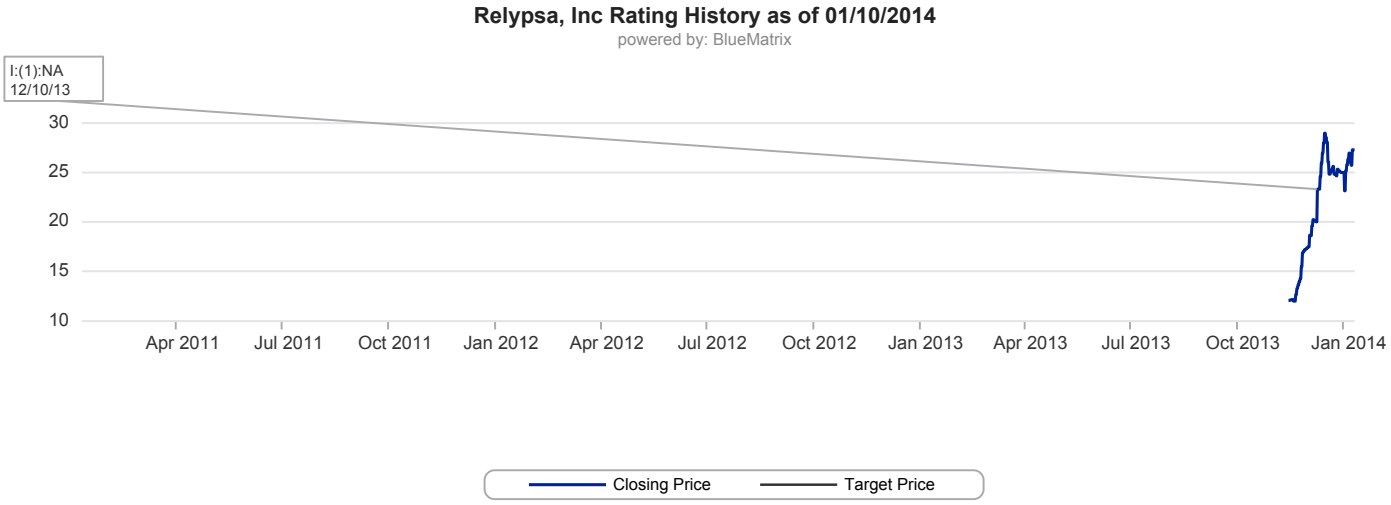
Cowen And Company Rating Definitions

Distribution of Ratings/Investment Banking Services (IB) as of 12/31/13

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	415	59.20%	68	16.39%
Hold (b)	270	38.52%	4	1.48%
Sell (c)	16	2.28%	1	6.25%

(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.

Note: "Buy", "Hold" and "Sell" are not terms that Cowen and Company, LLC uses in its ratings system and should not be construed as investment options. Rather, these ratings terms are used illustratively to comply with FINRA and NYSE regulations.



Legend for Price Chart:

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

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