COWEN
AND COMPANY

Biotechnology

Relypsa, Inc

Equity Research

Company Quick Take

May 12, 2014

Price: $19.60 (05/9/2014)

Price Target: NA

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: RLYP
Market Cap (MM)	$663.4

Positive Onset-Of-Action Study Prepares Patiromer For Q3 NDA

The Cowen Insight

Positive top-line data from patiromer's onset-of-action study position the drug as an add-on therapy in the acute setting and further bolster its tolerability advantage over Kayexalate. Completion of this trial enables an NDA submission for the much larger chronic hyperkalemia market in Q3:14. We expect the drug to launch ahead of competitors in H2:15.

The news: Relypsa released positive top-line data from the Phase 1 onset-of-action study assessing the ability of patiromer to lower blood potassium in CKD patients. The open-label, single-arm trial enrolled 25 CKD patients who were taking at least one RAAS inhibitor and had moderate to severe hyperkalemia (serum potassium levels of 5.5 to less than 6.5 mEq/L). In order to stabilize the dietary intake of potassium, the trial had a 3-day run-in period. Patiromer was administered twice daily (8.4 g/dose) over 48 hours. The patients were monitored during the treatment period followed by a 7-day post-treatment safety follow-up period. A statistically significant reduction from baseline in serum potassium levels was achieved within 7 hours after the start of treatment. Patiromer demonstrated a maximum mean reduction in serum potassium of 0.83 mEq/L from baseline (5.93 mEq/L). The subjects continued to maintain a safe level of serum potassium at all subsequent evaluations out to 48 hours, approximately 14 hours after the last dose ($p < 0.001$ at 48 hours). No serious adverse events or discontinuations were recorded.

Our Take: This onset-of-action study was requested by the FDA to provide doctors with comprehensive information on the uses of patiromer. While a necessary box to check ahead of NDA submission, the acute hyperkalemia setting does not represent a significant market opportunity for patiromer. Patiromer's efficacy and safety profile make it ideal for the chronic treatment of hyperkalemia, where the largest commercial opportunity lies. In the acute setting, emergency room doctors stabilize potassium levels of hyperkalemic patients using calcium gluconate, insulin and beta-agonists. These are fast acting drugs with limited protective effects (1-6 hours). Kayexalate is typically added on in this setting to achieve longer term serum potassium control. Given the similar onset of action demonstrated by patiromer and its superior tolerability profile compared to Kayexalate, we expect it to replace Kayexalate in this setting as well.

Investment Thesis: Relypsa plans to file an NDA on patiromer for the treatment of hyperkalemia in Q3:14. We expect patiromer to launch ahead of competitors in the second half of 2015. 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).

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, Inc

Analyst Certification

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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 03/31/14

Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	407	57.08%	85	20.88%
Hold (b)	288	40.39%	8	2.78%
Sell (c)	18	2.52%	1	5.56%

(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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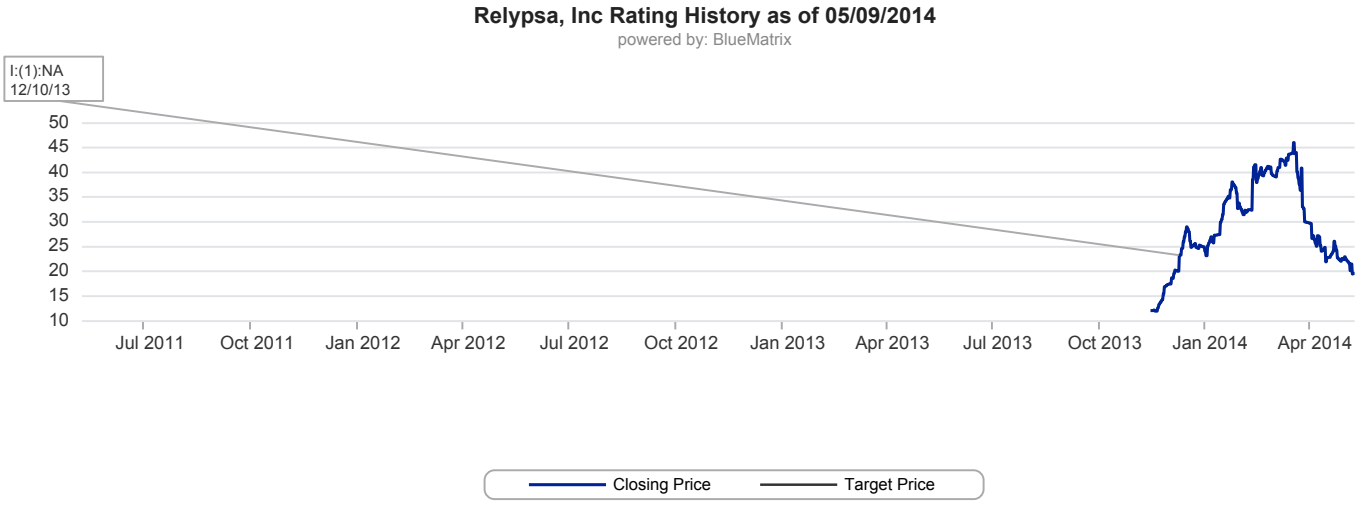

Legend for Price Chart:

I = Initation | 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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