COWEN
AND COMPANY

Biotechnology

Relypsa, Inc

Equity Research

Earnings Update

March 18, 2014

Price: $43.91 (03/17/2014)

Price Target: NA

OUTPERFORM (1)

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Key Data

Symbol	NASDAQ: RLYP
52-Week Range:	$46.81 - 11.00
Market Cap (MM):	$1,303.8
Net Debt (MM):	$(78.8)
Cash/Share:	$175.60
Dil. Shares Out (MM):	31.5
Enterprise Value (MM):	$1,446.4
ROIC:	NA
ROE (LTM):	NA
BV/Share:	NA
Dividend:	NA

FY (Dec)	2012A	2013A	2014E
Earnings Per Share			
Q1	$0.00	$(3.90)	$(0.52)
Prior Q1	-	-	*$(0.49)*
Q2	$0.00	$(4.79)	$(0.61)
Prior Q2	-	-	*$(0.49)*
Q3	$0.00	$(4.84)	$(0.72)
Prior Q3	-	*$(1.30)*	*$(0.51)*
Q4	$0.00	$(0.68)	$(0.79)
Prior Q4	-	*$(0.69)*	*$(0.61)*
Year	$(11.94)	$(22.42)	$(2.64)
Prior Year	-	*$(3.15)*	*$(2.10)*
P/E	NM	NM	NM
Consensus EPS	-	$(22.42)	$(2.12)
Prior Year	-	*$(3.41)*	-

Consensus source: Thomson Reuters

Reports Q4:13; Patiromer NDA On Track For Q3

The Cowen Insight

Relypsa reported Q4 results and provided 2014 financial guidance. Relypsa is completing one final trial on patiromer (a Phase I speed of onset study) and intends to file an NDA for the treatment of hyperkalemia in Q3. We believe patiromer has near $1B potential for this significant unmet need, and expect shares to outperform into a potential 2015 approval and product launch.

Relypsa Financed Into 2015

Relypsa reported a Q4 net loss of $9.1MM vs. our $19.3M estimate. Following a November 2013 IPO, Relypsa ended the year with $95MM in cash, enough to finance the company to patiromer's approval, though additional proceeds may be needed to support a launch. Operating expenses are expected to range from $75-95MM in 2014, inclusive of $5-10MM in stock based compensation. This guidance is consistent with our modeled assumptions.

Patiromer Looks Approvable For The Chronic Treatment For Hyperkalemia...

Patiromer is a nonabsorbed polymer that binds potassium in the gut and excretes it from the body. The drug is being developed for the chronic treatment of hyperkalemia, a condition characterized by elevated serum potassium levels. Patients with chronic kidney disease and heart failure are known to have elevated levels of potassium, which carry risk of cardiac arrhythmia and sudden death. Unfortunately, RAASi therapies (ARBs, ACE inhibitors, AAs) that are the standard of care for treating these diseases further exacerbate the situation by increasing blood levels of potassium. As a result, RAASi therapies are often underdosed, providing for sub optimal control of the underlying disease.

Patiromer has been tested in five clinical trials establishing a safety database of approximately 726 subjects. In an SPA-sponsored Phase III trial, patiromer reduced serum potassium to normal ranges in 76% of patients. Moreover, supporting a clinical benefit for patiromer, results from the exploratory endpoints of the pivotal trial showed that significantly more placebo patients required dose modification of their RAASi therapies (62%) compared to patiromer patients (6%), $p<0.001$. At the end of the trial, 94% of patiromer patients were still on RAASi therapy, as opposed to only 48% of placebo patients $p<0.001$. Unlike other potassium lowering therapeutics, the drug appears well tolerated and safe for chronic use. The rate limiting factor for NDA submission is the completion of one last Phase I trial, which the FDA requested in order to establish how quickly patiromer can impact hyperkalemia.

...And Addresses A Sizeable Opportunity

Over 2M moderate to severe hyperkalemia patients present to specialists. We project that patiromer will capture 0.6% of its U.S. opportunity in 2016, growing to 5.0% by 2022. Assuming pricing of $6,400/year and a 50% compliance rate, we project U.S. sales of nearly $600 million by 2022 ramping to ~$1B over time.

At A Glance

Our Investment Thesis

Relypsa plans to file an NDA on patiromer for the treatment of hyperkalemia in Q3:14. 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 view RLYP shares as 29% undervalued based upon a sum of the parts methodology.

Forthcoming Catalysts

- Complete Phase I onset of action trial
- File patiromer NDA
- Possible FDA AdCom meeting on patiromer

Base Case Assumptions

- Patiromer is approved for treating hyperkalemia
- Patiromer achieves 2018 U.S. sales of $200MM

Upside Scenario

- Patiromer's launch proceeds better than expected
- Relypsa is able to monetize patiromer's value outside the U.S.
- Relypsa is able to generate other interesting drug candidates

Downside Scenario

- Patiromer encounters regulatory delays or setbacks
- Patiromer's side effect profile worsens
- Patiromer's launch falls short of expectations

Price Performance

Source: Bloomberg

Company Description

Relypsa is developing patiromer for the treatment of hyperkalemia (high levels of potassium in the blood). Patients with chronic kidney disease and heart failure are known to have elevated levels of potassium, which carry risk of cardiac arrhythmia and sudden death. Unfortunately, RAASi therapies (ARBs, ACE inhibitors, AAs) that are the standard of care for treating these diseases further exacerbate the situation by increasing blood levels of potassium. As a result, RAASi therapies are often under-dosed, providing for sub optimal control of the underlying disease. Patiromer is a non-absorbed polymer that binds potassium in the gut and excretes it from the body. In an SPA-sponsored Phase III trial, patiromer reduced serum potassium to normal ranges in 76% of patients. Unlike other potassium lowering therapeutics, the drug appears well tolerated and safe for chronic use. Therefore, we believe patiromer represents an approvable therapy for an unmet need.

Analyst Top Picks

	Ticker	Price (03/17/2014)	Price Target	Rating
Amgen	AMGN	$123.86	$131.00	Outperform
Biogen Idec	BIIB	$345.60	$372.00	Outperform
Incyte	INCY	$62.22	$NA	Outperform

Investment Thesis

Relypsa is developing patiromer for the treatment of hyperkalemia (high levels of potassium in the blood). Patients with chronic kidney disease and heart failure are known to have elevated levels of potassium, which carry risk of cardiac arrhythmia and sudden death. Unfortunately, RAASi therapies (ARBs, ACE inhibitors, AAs) that are the standard of care for treating these diseases further exacerbate the situation by increasing blood levels of potassium. As a result, RAASi therapies are often under dosed, providing for sub optimal control of the underlying disease. Patiromer is a nonabsorbed polymer that binds potassium in the gut and excretes it from the body. In an SPA-sponsored Phase III trial, patiromer reduced serum potassium to normal ranges in 76% of patients. Unlike other potassium lowering therapeutics, the drug appears well tolerated and safe for chronic use. Therefore, we believe patiromer represents an approvable therapy for an unmet need. Relypsa plans to file an NDA on patiromer for the treatment of hyperkalemia in Q3:14. 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 patiromer advances toward potential FDA approval in 2015.

Upcoming Relypsa Milestones

Event	Timing
Complete Phase I onset of action trial on patiromer	Q2:14
Submit patiromer NDA	Q3:14
Potential selection of additional polymer-based development candidates	2014-2015
Possible FDA advisory panel for patiromer	H1:15
U.S. approval and launch of patiromer	Q4:15

Source: Cowen and Company

Relypsa Quarterly P&L ($MM)

	Q1:13A	Q2:13A	Q3:13A	Q4:13A	2013A	Q1:14E	Q2:14E	Q3:14E	Q4:14E	2014E
Relypsa Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Revenue	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Y/Y growth										
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
GMs										
R&D	16.3	19.6	12.2	10.9	59.0	12.0	14.2	16.0	17.0	59.2
SG&A	2.0	3.5	2.7	3.7	11.9	4.0	4.7	6.5	8.0	23.2
Total Expenses	**18.3**	**23.1**	**14.8**	**14.6**	**70.9**	**16.0**	**18.9**	**22.5**	**25.000**	**82.4**
Operating Income/Loss	**(18.3)**	**(23.1)**	**(14.8)**	**(14.6)**	**(70.9)**	**(16.0)**	**(18.9)**	**(22.5)**	**(25.0)**	**(82.4)**
Non-Operating Income	(2.5)	(2.5)	(10.8)	5.6	(10.3)	(0.4)	(0.4)	(0.4)	(0.4)	(1.6)
Pre-tax Income/Loss	**(20.8)**	**(25.6)**	**(25.6)**	**(9.1)**	**(81.2)**	**(16.4)**	**(19.3)**	**(22.9)**	**(25.4)**	**(84.0)**
Tax rate (%)	0%	0%	0%	0%	0%	0%	0%	8%	0%	0%
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	**(20.8)**	**(25.6)**	**(25.6)**	**(9.1)**	**(81.2)**	**(16.4)**	**(19.3)**	**(22.9)**	**(25.4)**	**(84.0)**
GAAP EPS	**($3.90)**	**($4.79)**	**($4.84)**	**$ (0.68)**	**$ (22.42)**	**($0.52)**	**($0.61)**	**($0.72)**	**($0.79)**	**($2.64)**
Diluted Shares	5.3	5.3	5.3	13.4	3.6	31.5	31.7	31.9	32.0	31.8

Source: Cowen and Company

Relypsa Annual P&L Model ($MM)

	2013A	2014E	2015E	2016E	2017E	2018E
Relypsa Revenue	0.0	0.0	5.0	50.0	125.0	200.0
Total Revenue	**0.0**	**0.0**	**5.0**	**50.0**	**125.0**	**200.0**
Y/Y growth	0%	0%	0%	900%	150%	60%
COGS	0.0	0.0	1.8	11.9	23.5	34.0
R&D	59.0	59.2	56.0	60.0	64.0	67.0
SG&A	11.9	23.2	51.0	84.5	90.0	95.0
Total Expenses	**70.9**	**82.4**	**108.8**	**156.4**	**177.5**	**196.0**
Operating Income/Loss	(70.9)	(82.4)	(103.8)	(106.4)	(52.5)	4.0
Non-Operating Income	(10.3)	(1.6)	(1.6)	(2.0)	(2.0)	(2.0)
Pre-tax Income/Loss	(81.2)	(84.0)	(105.4)	(108.4)	(54.5)	2.0
Tax rate (%)	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	(81.2)	(84.0)	(105.4)	(108.4)	(54.5)	2.0
GAAP EPS	**($22.42)**	**($2.64)**	**($2.85)**	**($2.85)**	**($1.40)**	**$0.05**
Diluted Shares	3.6	31.8	37.0	38.0	39.0	41.0

Source: Cowen and Company

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.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon a 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 it there are any good methodologies for assigning a specific target price to such stocks.

Addendum

Stocks Mentioned In Important Disclosures

Ticker	Company Name
AMGN	Amgen
BIIB	Biogen Idec
INCY	Incyte
RLYP	Relypsa, Inc

Analyst Certification

Each author of this research report hereby certifies that (i) the views expressed in the research report accurately reflect his or her personal views about any and all of the subject securities or issuers, and (ii) no part of his or her compensation was, is, or will be related, directly or indirectly, to the specific recommendations or views expressed in this report.

Important Disclosures

Cowen and Company, LLC and or its affiliates make a market in the stock of Relypsa, Inc, Amgen, Biogen Idec and Incyte securities.

Relypsa, Inc and Incyte have been client(s) of Cowen and Company, LLC in the past 12 months.

Relypsa, Inc and Incyte is or was in the past 12 months a client of Cowen and Company, LLC; during the past 12 months, Cowen and Company, LLC provided IB services.

Cowen and Company, LLC and/or its affiliates received in the past 12 months compensation for investment banking services from Relypsa, Inc and Incyte.

Cowen and Company, LLC and/or its affiliates managed or co-managed a public offering of Relypsa, Inc and Incyte within the past twelve months.

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Cowen and Company Rating System effective May 25, 2013

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

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

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

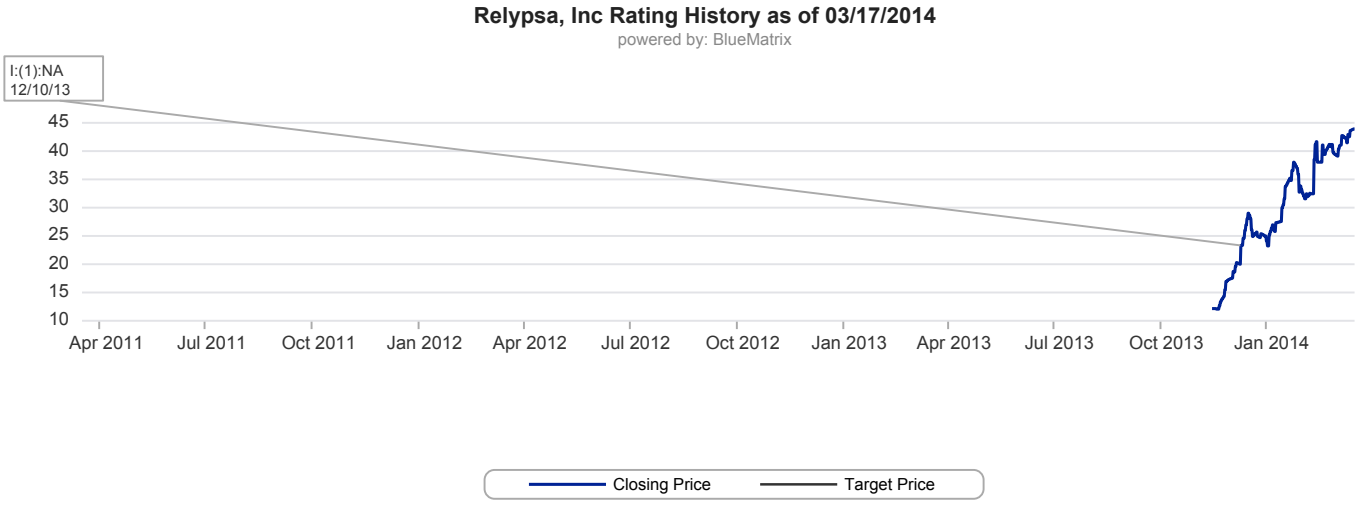
Cowen And Company Rating Definitions

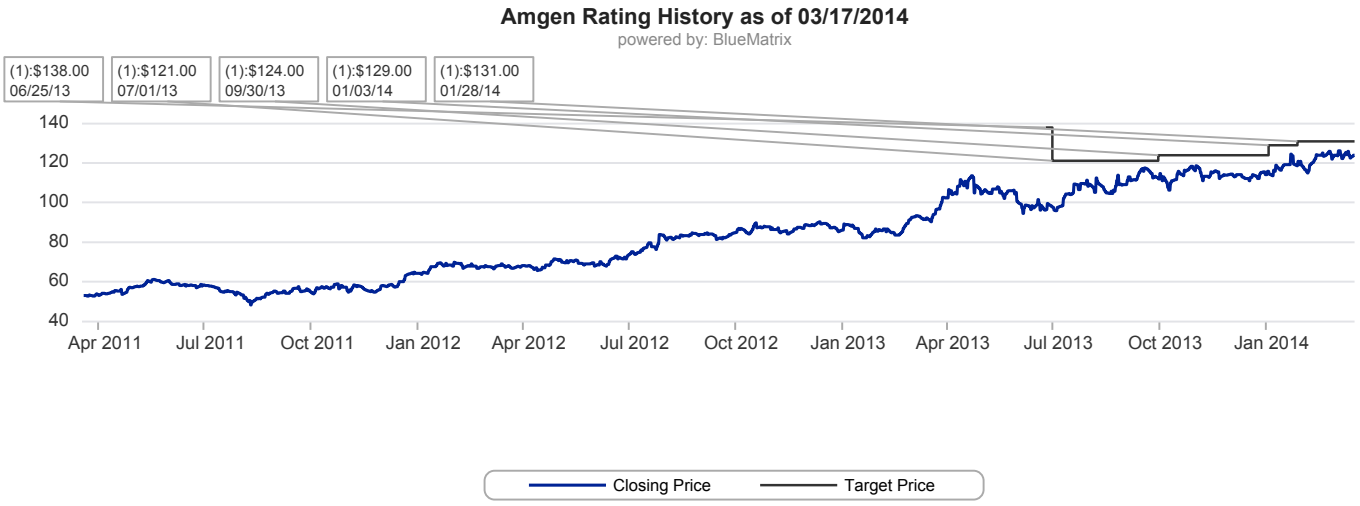
Distribution of Ratings/Investment Banking Services (IB) as of 12/31/13

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.





Biogen Idec Rating History as of 03/17/2014

powered by: BlueMatrix

Rating Change - 10/28/2008 - Rating Outperform

Incyte Rating History as of 03/17/2014

powered by: BlueMatrix

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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