

Equity Research

March 24, 2014

**Price: \$55.05** (03/21/2014)

**Price Target: NA**

**OUTPERFORM (1)**

**Eric Schmidt, Ph.D.**

646.562.1345

eric.schmidt@cowen.com

**Key Data**

Symbol	NASDAQ: RARE
52-Week Range:	\$69.77 - 35.15
Market Cap (MM):	\$1,647.4
Net Debt (MM):	\$0.0
Cash/Share:	\$24.92
Dil. Shares Out (MM):	3.7
Enterprise Value (MM):	\$1,701.8
ROIC:	NA
ROE (LTM):	NA
BV/Share:	\$(15.35)
Dividend:	NA

FY (Dec)	2013A	2014E	2015E
<b>Earnings Per Share</b>			
Q1	\$(2.87)	\$(0.40)	-
Prior Q1	\$(0.37)	-	-
Q2	\$(3.44)	\$(0.44)	-
Prior Q2	\$(0.45)	-	-
Q3	\$(3.39)	\$(0.45)	-
Prior Q3	\$(0.44)	-	-
Q4	\$(4.98)	\$(0.50)	-
Prior Q4	\$(0.34)	-	-
Year	\$(14.87)	\$(1.80)	\$(1.90)
Prior Year	\$(1.60)	-	-
P/E	NM	NM	NM

<b>Revenue (MM)</b>			
Q1	\$0.0	\$0.0	-
Q2	\$0.0	\$0.0	-
Q3	\$0.0	\$0.0	-
Q4	\$0.0	\$0.0	-
Year	\$0.0	\$0.0	\$0.0

Earnings Update

# Ultragenyx Sticks to the Plan

## The Cowen Insight

Ultragenyx released its Q4 results and provided an update on its clinical development programs. Financials were generally as expected. Development continues on schedule for Ultragenyx's 4 Phase II candidates (KRN23, rhGUS, SA-ER, and triheptanoin) in 5 indications. Data flow is expected throughout the next 2 years. We believe Ultragenyx will become a leading rare metabolic disorder company.

## Financial Update:

This morning, Ultragenyx reported Q4:13 results. Ultragenyx generated an operating loss of \$9.5MM versus our \$8.0MME. Non-operating expenses generated a net loss of \$11.3MM versus our \$8.5MME. Ultragenyx ended 2013 with \$53.4MM in cash. This cash balance combined with the \$121.7MM raised in February's IPO are anticipated to fund operations into 2016.

## Lead Biologic Programs:

MPS7 is caused by a mutation which compromises beta-glucuronidase (GUS) activity. Enrollment of the Phase I/II trial of Ultragenyx's rhGUS in MPS7 (a \$100MM market opportunity) will continue during H1:14. Initial changes in urinary glycosaminoglycans for the first three patients will be released later this month. Interim 12-week efficacy data will be released in H2:14 and could support the initiation of a pivotal trial before YE:14. X-linked hypophosphatemia (XLH) is caused by mutations leading to excessive FGF23 production. During 2014, Ultragenyx plans to release Phase I/II repeat dosing data for its anti-FGF23 antibody (KRN23) as well as initiate a Phase II trial of KRN23 in pediatric XLH patients. We estimate KRN23 could generate as \$400MM+ in revenue for Ultragenyx.

## Triheptanoin Update:

Triheptanoin is a seven carbon chain fatty acid being developed as an alternative energy source for patients with orphan energy disorders. Ultragenyx initiated Phase 2 trials of triheptanoin in long-chain fatty acid disorders (LC-FAOD) and glucose transporter type-1 deficiency syndrome (Glut1 DS) in February and March respectively. Data from each trial is expected in 2015. We believe triheptanoin should prove superior to existing dietary alternatives with LC-FAOD and Glut1 DS each representing \$400MM+ markets.

## Sialic Acid-Extended Release (SA-ER) Update:

Hereditary Inclusion Body Myopathy (HIBM) is a disorder where inclusion bodies accumulate in muscle fibers leading to progressive muscle atrophy. A defect in sialic acid biosynthesis is believed to be responsible for the generation of inclusion bodies. As part of an ongoing Phase II study, Ultragenyx previously reported modest benefits in muscle strength following 48-weeks of SA-ER therapy. Ultragenyx has since expanded the trial to include a higher daily sialic acid dosage. The 48-week data is due to be presented as a late-breaker at the American Academy of Neurology meeting in April. Data from the trial expansion is expected later in 2014.

## At A Glance

### Our Investment Thesis

KRN23's animal model and early human (Phase I) data are compelling, and we view it as a relatively low-risk candidate with >\$1B in worldwide potential. Triheptanoin's metabolic profile should prove superior to existing dietary alternatives, and early clinical data support this view. FAOD and Glut1 DS could each represent \$400MM + markets for triheptanoin. SA-ER, and extended release form of sialic acid, is in a randomized Phase II trial for HIBM, a rare muscle disease. Initial data from the study have produced intriguing signs of activity. Ultragenyx is financed into 2016 and through potential value creating milestones on all of its programs. We expect the stock to outperform as milestones on these and other programs are achieved.

### Forthcoming Catalysts

- Phase I/II repeat dosing data for KRN23 in adult XLH patients
- Phase I/II data for rhGUS in MPS7
- Data from Phase II trial extension of SA-ER in HIBM in late 2014

### Base Case Assumptions

- KRN23 is launched in 2018; achieves sales of over \$1B in XLH
- Triheptanoin is launched for Glut1 DS in 2018 and LC-FAOD in 2019; achieves nearly \$1B in sales by 2027
- rhGUS is launched in 2017 for MPS7; achieves \$100MM in sales by 2027

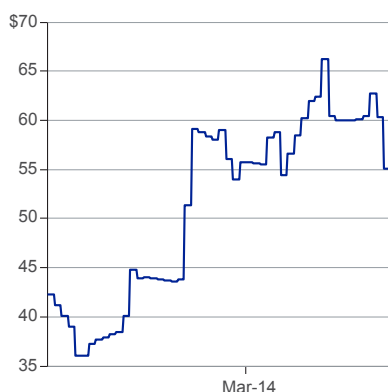
### Upside Scenario

- SA-ER demonstrates clear efficacy in HIBM; achieves commercial success
- Triheptanoin demonstrates a cognitive benefit for Glut1 DS patients
- Increased screening expands the diagnosed ex-U.S. LC-FAOD patient population

### Downside Scenario

- Repeat dosing of KRN23 generates anti-KRN23 antibodies
- Triheptanoin fails to demonstrate a benefit in Glut1 DS patients
- Orphan drug pricing comes under pressure

### Price Performance



Source: Bloomberg

### Company Description

Ultragenyx is focused on developing novel therapeutics for rare, serious metabolic disorders. Ultragenyx has built a multi-faceted pipeline via business development that contains four clinical candidates for five indications. KRN23 is a monoclonal antibody specific for FGF23 being developed for X-linked hypophosphatemia (XLH) under a collaboration with Kirin. KRN23 is currently in Phase I/II trials expected to readout in 2014. Triheptanoin is a wholly owned 7-chain carbon alternative source of energy in Phase II trials for long-chain fatty acid oxidation disorders (LC-FAOD) and glucose transporter 1 deficiency (Glut1 DS). Data for both indications is anticipated for 2015. rhGUS is an enzyme replacement therapy in Phase I for the lysosomal storage disease MPS7. Data is expected in H2:14, and could propel rhGUS straight into Phase III. Finally, sialic acid extended release (SA-ER) is in Phase II trials for HIBM which is proposed to be driven by a lack of sialic acid.

### Analyst Top Picks

	Ticker	Price (03/21/2014)	Price Target	Rating
Sunesis Pharmaceuticals	SNSS	\$6.95	\$NA	Outperform
Relypsa, Inc	RLYP	\$40.09	\$NA	Outperform
Ultragenyx	RARE	\$55.05	\$NA	Outperform

## Investment Thesis

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Ultragenyx is focused on developing novel therapeutics for rare, serious metabolic disorders. Ultragenyx has built a multi-faceted pipeline via business development that contains four clinical candidates for five indications. KRN23 is a monoclonal antibody specific for FGF23 being developed for X-linked hypophosphatemia (XLH) under a collaboration with Kirin. KRN23 is currently in Phase I/II trials expected to readout in 2014. KRN23's animal model and early human (Phase I) data are compelling, and we view it as a relatively low-risk candidate with >\$1B in worldwide potential.

Triheptanoin is a wholly owned 7-chain carbon alternative source of energy in Phase II trials for long-chain fatty acid oxidation disorders (LC-FAOD) and glucose transporter 1 deficiency (Glut1 DS). Data for both indications is anticipated for 2015.

Triheptanoin's metabolic profile should prove superior to existing dietary alternatives, and early clinical data support this view. FAOD and Glut1 DS could each represent \$400MM+ markets for triheptanoin. rhGUS is an enzyme replacement therapy in Phase I for the lysosomal storage disease MPS7. Data is expected in H2:14, and could propel rhGUS straight into a Phase III trial. Finally, sialic acid extended release (SA-ER) is an extended release form of sialic acid. SA-ER is in a randomized Phase II trial for HIBM, a rare muscle disease. Initial data from a randomized Phase II study have produced intriguing signs of activity. Ultragenyx is financed into 2016 and through potential value creating milestones on all of its programs. We expect the stock to outperform as milestones on these and other programs are achieved.

#### Ultragenyx - Upcoming Milestones/Events

Indication/Milestone	Timing
Urinary glycosaminoglycan data from first 3 MPS7 patients	March 2014
Present 48-week data for UX001 (SA-ER) in HIBM	April 30, 2014
12-week Phase I/II data for UX003 (rhGUS) in MPS7	H2:14
Initiate KRN23 Phase II trial in pediatric XLH	H2:14
Discussions with the FDA regarding uGAG as a Phase III endpoint for MPS7	H2:14
Data from the Phase II extension study of UX001 (SA-ER) in HIBM	Late 2014
Phase I/II repeat dosing data for KRN23 in adult XLH	2014
24-week data from UX007 (triheptanoin) trial in LC-FAOD	2015
Phase II data for KRN23 in pediatric XLH	2015
Phase III data for UX003 (rhGUS) in MPS7	2015
8-week data from UX007 (triheptanoin) trial in Glut1 DS	2015

Source: Cowen and Company

## Ultragenyx Quarterly P&L

	Q1:13A	Q2:13A	Q3:13A	Q4:13A	2013A	Q1:14E	Q2:14E	Q3:14E	Q4:14E	2014E
KRN23 Revenue										
Triheptanoin Revenue										
rhGUS Revenue										
Collaborative/Grant/Other Revenue										
<b>Total Revenue</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>
<i>Y/Y growth</i>										
COGS	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<i>GMs</i>										
R&D	5.7	7.2	6.8	8.2	27.8	9.0	10.5	11.0	12.0	42.5
SG&A	1.1	1.0	1.0	1.3	4.5	2.5	3.0	3.0	3.5	12.0
<b>Total Expenses</b>	<b>6.7</b>	<b>8.2</b>	<b>7.8</b>	<b>9.5</b>	<b>32.3</b>	<b>11.5</b>	<b>13.5</b>	<b>14.0</b>	<b>15.5</b>	<b>54.5</b>
<b>Operating Income/Loss</b>	<b>(6.7)</b>	<b>(8.2)</b>	<b>(7.8)</b>	<b>(9.5)</b>	<b>(32.3)</b>	<b>(11.5)</b>	<b>(13.5)</b>	<b>(14.0)</b>	<b>(15.5)</b>	<b>(54.5)</b>
Interest Income/Expense	0.0	0.1	0.1	0.0	0.2	0.0	0.0	0.0	0.0	0.0
Other Income/Expense	(0.0)	(0.4)	(0.7)	(1.8)	(2.9)	(0.5)	(0.5)	(0.5)	(0.5)	(2.0)
Pre-tax Income/Loss	(6.7)	(8.6)	(8.4)	(11.3)	(35.1)	(12.0)	(14.0)	(14.5)	(16.0)	(56.5)
<i>Tax rate (%)</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>	<i>0%</i>
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income (Loss)</b>	<b>(6.7)</b>	<b>(8.6)</b>	<b>(8.4)</b>	<b>(11.3)</b>	<b>(35.1)</b>	<b>(12.0)</b>	<b>(14.0)</b>	<b>(14.5)</b>	<b>(16.0)</b>	<b>(56.5)</b>
Accretion and dividends on convertible preferred stock	(2.6)	(2.6)	(2.6)	(7.3)	(15.2)	0.0	0.0	0.0	0.0	0.0
<b>Net Income (Loss) attributable to common stockholders</b>	<b>(9.4)</b>	<b>(11.2)</b>	<b>(11.1)</b>	<b>(18.7)</b>	<b>(50.3)</b>	<b>(12.0)</b>	<b>(14.0)</b>	<b>(14.5)</b>	<b>(16.0)</b>	<b>(56.5)</b>
<b>GAAP EPS</b>	<b>(\$2.87)</b>	<b>(\$3.44)</b>	<b>(\$3.39)</b>	<b>(\$4.98)</b>	<b>(\$14.87)</b>	<b>(\$0.40)</b>	<b>(\$0.44)</b>	<b>(\$0.45)</b>	<b>(\$0.50)</b>	<b>(\$1.80)</b>
Diluted Shares	3.3	3.3	3.3	3.7	3.4	30.0	31.8	31.9	32.1	31.5

Source: Cowen and Company

## Ultragenyx Annual P&L

	2013A	2014E	2015E	2016E	2017E	2018E
KRN23 Revenue	0.0	0.0	0.0	0.0	0.0	0.0
Triheptanoin Revenue	0.0	0.0	0.0	0.0	0.0	20.0
rhGUS Revenue	0.0	0.0	0.0	0.0	11.0	29.0
Collaborative/Grant/Other Revenue	0.0	0.0	0.0	0.0	0.0	0.0
<b>Total Revenue</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>0.0</b>	<b>11.0</b>	<b>49.0</b>
COGS	0.0	0.0	0.0	0.0	2.0	7.6
<i>GMs</i>					<i>0.8</i>	<i>0.8</i>
R&D	27.8	42.5	50.0	65.0	70.0	73.0
<b>Total Expenses</b>	<b>32.3</b>	<b>54.5</b>	<b>65.5</b>	<b>83.0</b>	<b>112.0</b>	<b>140.6</b>
<b>Operating Income/Loss</b>	<b>(32.3)</b>	<b>(54.5)</b>	<b>(65.5)</b>	<b>(83.0)</b>	<b>(101.0)</b>	<b>(91.6)</b>
Interest Income/Expense	0.2	0.0	0.0	0.0	0.0	0.0
Other Income/Expense	(2.9)	(2.0)	(1.0)	(0.3)	(0.3)	(0.3)
Pre-tax Income/Loss	(35.1)	(56.5)	(66.5)	(83.3)	(101.3)	(91.9)
Provision for income taxes	0.0	0.0	0.0	0.0	0.0	0.0
<b>Net Income (Loss)</b>	<b>(35.1)</b>	<b>(56.5)</b>	<b>(66.5)</b>	<b>(83.3)</b>	<b>(101.3)</b>	<b>(91.9)</b>
Accretion and dividends on convertible preferred stock	(15.2)	0.0	0.0	0.0	0.0	0.0
<b>Net Income (Loss) attributable to common stockholders</b>	<b>(50.3)</b>	<b>(56.5)</b>	<b>(66.5)</b>	<b>(83.3)</b>	<b>(101.3)</b>	<b>(91.9)</b>
<b>GAAP EPS</b>	<b>(\$14.87)</b>	<b>(\$1.80)</b>	<b>(\$1.90)</b>	<b>(\$2.25)</b>	<b>(\$2.60)</b>	<b>(\$2.30)</b>
Diluted Shares	3.4	31.5	35.0	37.0	39.0	40.0

Source: Cowen and Company

## *Valuation Methodology And Risks*

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### **Valuation Methodology**

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#### **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**

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#### **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**

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Investing in development stage biotechnology companies is risky, and many things could prevent Ultragenyx from achieving the success we model.

# Addendum

## Stocks Mentioned In Important Disclosures

Ticker	Company Name
RLYP	Relypsa, Inc
SNSS	Sunesis Pharmaceuticals
RARE	Ultragenyx

## Analyst Certification

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Sunesis Pharmaceuticals 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 Non-Security services.

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**Cowen and Company, LLC.** New York (646) 562-1000 **Boston** (617) 946-3700 **San Francisco** (415) 646-7200 **Chicago** (312) 577-2240 **Cleveland** (440) 331-3531 **Atlanta** (866) 544-7009 **London** (affiliate) 44-207-071-7500

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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.

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### Ultragenyx Rating History as of 03/21/2014

powered by: BlueMatrix



### Relypsa, Inc Rating History as of 03/21/2014

powered by: BlueMatrix





### Sunesis Pharmaceuticals Rating History as of 03/21/2014

powered by: BlueMatrix



Rating Change - 2/21/2006 - Outperform Rating

#### 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

## Points Of Contact

### Analyst Profiles



**Eric Schmidt, Ph.D.**

New York

646.562.1345

eric.schmidt@cowen.com

Eric Schmidt is a senior analyst covering the biotechnology sector. He joined Cowen in 1998, having previously worked at UBS Securities.

### Reaching Cowen

#### Main U.S. Locations

##### New York

599 Lexington Avenue  
New York, NY 10022  
646.562.1000  
800.221.5616

##### Atlanta

3399 Peachtree Road NE  
Suite 417  
Atlanta, GA 30326  
866.544.7009

##### Boston

Two International Place  
Boston, MA 02110  
617.946.3700  
800.343.7068

##### Chicago

181 West Madison Street  
Suite 1925  
Chicago, IL 60602  
312.577.2240

##### Cleveland

20006 Detroit Road  
Suite 100  
Rocky River, OH 44116  
440.331.3531

##### Houston

600 Travis Street  
Suite 1970  
Houston, TX 77002  
281.657.6800

##### San Francisco

555 California Street, 5th Floor  
San Francisco, CA 94104  
415.646.7200  
800.858.9316

#### International Locations

##### Cowen International Limited

###### London

1 Snowden Street - 11th Floor  
London EC2A 2DQ  
United Kingdom  
44.20.7071.7500

##### Cowen and Company (Asia) Limited

###### Hong Kong

Suite 1401 Henley Building  
No. 5 Queens Road Central  
Central, Hong Kong  
852 3752 2333

