Ultragenyx

KRN23 Multi-Dose Data Validates POC Ahead of Pediatric Trial Start

Overweight

RARE, RARE US
Price: $44.77

Price Target: $66.00

This morning at ICE/ENDO (6/21-6/24, Chicago), RARE presented data from the Phase 1/2 trial of KRN23 (partnered with KHK) in X-linked hypophosphatemia (XLH). This dataset (which is in line with the abstract) gives us our first look at multi-dose performance for the drug, and shows encouraging efficacy, safety, and QoL effects in adult patients. We note, however, that the largest revenue opportunity in this indication is likely to come from pediatric patients (Phase 2 trial to start 2H14), and as such we view this data largely as positive POC for the mechanism ahead of trials in that patient population. We would also point out that this trial had been completed (and RARE had access to the data) prior to signing the collaboration agreement with KHK. Thus we are not surprised that these data are positive/supportive of further development, but think investors will nonetheless be encouraged by the further de-risking of a key pipeline asset. Of RARE's 5 clinical programs, we continue to think KRN23 has one of the highest probabilities of success (we model 65%), representing peak revenue opportunity of ~$800M. Reiterate Overweight.

- **Repeat KRN23 doses led to increases in serum phosphorus in 100% of pts, with 89% reaching the normal range (low end).** The Phase 1/2, dose-escalating trial enrolled 28 adult XLH patients who were administered up to 4 once-monthly doses of KRN23 (an FGF23 mAb). The multi-dose data validates the single-dose data, showing that blocking excess FGF23 is effective in improving phosphate metabolism/increasing serum phosphorus (Pi) levels over time. After 4 months of treatment, peak mean serum Pi increased 60% (up to 3.03±0.42 from 1.89±0.33mg/dL), with comparable increases in tubular re-absorption of phosphorus (TmP/GFR) and serum vitamin D.

- **Repeat dosing of KRN23 was relatively safe and well tolerated, and longer-term data indicates continued safety/effect on serum phosphorus.** Importantly there were no clinically significant changes in PTH, serum calcium, or urinary calcium excretion, and no clinically significant renal or cardiac calcification was observed. Additionally, there were no treatment-related SAEs and no anti-KRN23 antibodies were detected in trial subjects. QoL assessments indicated stat sig improvements in key measures, which will be further adjudicated in future trials. 22 patients from the current trial were enrolled in a long-term Phase 1/2 trial to evaluate an additional 12 doses of KRN23. The PR indicates the drug effect was sustained and the safety profile continued to be favorable, and full data is expected to be presented at ASBMR (9/12-15; Houston).

Biotechnology

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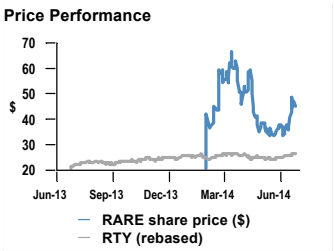

	YTD	1m	3m	12m
Abs	113.2 %	27.2%	-18.7%	113.2 %
Rel	111.4 %	22.0%	-18.0%	88.6%

Ultragenyx Pharmaceutical (RARE;RARE US)

FYE Dec	2013A	2014E	2015E
EPS Reported ($)			
Q1 (Mar)	-	(0.85)A	-
Q2 (Jun)	-	(0.45)	-
Q3 (Sep)	-	(0.55)	-
Q4 (Dec)	-	(0.63)	-
FY	(14.87)	(2.41)	(2.28)

Source: Company data, Bloomberg, J.P. Morgan estimates.

Company Data	
Price ($)	44.77
Date Of Price	23 Jun 14
52-week Range ($)	69.77-32.02
Market Cap ($ mn)	966.25
Fiscal Year End	Dec
Shares O/S (mn)	22
Price Target ($)	66.00
Price Target End Date	31-Dec-14

See page 5 for analyst certification and important disclosures.

- **KRN23's impact on bone remodeling markers highlights potential to prevent skeletal deformities in pediatric pts.** Given that low serum phosphorus during developmental years is the cause for characteristic skeletal deformities in XLH, KRN23's potential benefit on bone formation could be key in pediatric patients. A statistically significant ($p<0.05$) increase from baseline in P1NP (a marker of bone formation) was observed after all doses, and a stat sig increase in osteocalcin ($p<0.05$) was observed after the 4th dose. Increases in other markers of bone remodeling were also observed.

- **Pediatric XLH likely provides largest revenue opportunity; Phase 2 trial on track to start in 2H14.** Ultragenyx estimates that there are ~3,000 XLH pediatric patients and ~9,000 XLH adult patients in the US, though we assume a higher treatment rate in a pediatric population given pediatric patients with XLH have the highest morbidity and thus potential to benefit (and many adults may not seek treatment). In the US, we assume a penetration of 70% and 10% in peds and adults, respectively. ROW, we assume an average 20% penetration rate across all XLH patients. Regarding price, we assume a base case price of $100K per patient, which translates into peak sales of ~$800 million.

- **Upcoming events: Long-term Phase 1/2 KRN23 data to be presented in Sept.** Data from the long-term Phase 1/2 trial of KRN23 will be presented at ASBMR in September. Interim Phase 1/2 data for rhGUS in MPS 7 is anticipated in 2H14. Phase 2 extension study data for SA-ER in HIBM should read out by YE14. In addition, a number of trial initiations are expected this year, including a Phase 2 pediatric trial of KRN23 in XLH and a Phase 3 study of rhGUS in MPS 7. RARE expects data from the recently initiated Phase 2 studies of triheptanoin in both LC-FAOD and Glut1 DS in 2015.

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Investment Thesis, Valuation and Risks

Ultragenyx *(Overweight; Price Target: $66.00)*

Investment Thesis

We have an OW rating on RARE. We believe RARE is uniquely positioned with a broad and diverse pipeline of orphan disease assets and a highly regarded management team with a strong track record in the space. The company has five product candidates focused on orphan indications with a high unmet medical need, which provides both diversification and increased probability of ultimate success, in our view.

Valuation

Our probability weighted Dec-14 PT of $66 is based on a blended average of our proprietary probability-adjusted sum-of-the-parts scenario analysis (50% weighting) and risk-adjusted NPV model (50% weighting).

RARE Valuation Summary

Ultragenyx Valuation Summary

Discount rate	10.0%		
4Q14 Fully Diluted Shares (mm)	36.2		
Main value drivers	Prob of approval	Peak WW sales est (avg. scenario)	Avg peak yr
KRN23	65%	$ 275	2024
rhGUS	75%	$ 75	2022
Tripheptanoin (FAOD)	45%	$ 300	2024
Tripheptanoin (Glut1 DS)	45%	$ 825	2024
SA-ER	30%	$ 125	2022
Valuation methodology	Value / share	Weighting	Adj. value/ share
Real options scenario analysis	$ 69.15	50%	34.57
Risk adjusted NPV analysis	$ 62.75	50%	31.37
Total		100%	$ 65.95
Catalyst/liquidity discount			0%
YE14 Price Target			**$ 66**

Source: J.P. Morgan estimates.

Risks to Rating and Price Target

RARE is susceptible to the standard risks that apply to the entire biotech industry, including development, regulatory, commercial, manufacturing, financing, and IP pitfalls. More specific risks to the downside include clinical setbacks for key candidates (incl KRN23, rhGUS, tripheptanoin, and SA-ER), regulatory hurdles, commercial setbacks, and personnel risk.

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Ultragenyx: Summary of Financials

Income Statement - Annual	FY13A	FY14E	FY15E	FY16E	Income Statement - Quarterly	1Q14A	2Q14E	3Q14E	4Q14E
Revenues	0	0	0	0	Revenues	0A	0	0	0
Cost of products sold	0	0	0	0	Cost of products sold	0A	0	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(4)	(15)	(17)	(24)	SG&A	(2)A	(3)	(4)	(5)
R&D	(28)	(45)	(57)	(70)	R&D	(8)A	(10)	(12)	(14)
Operating income	(32)	(59)	(74)	(94)	Operating income	(10)A	(14)	(17)	(19)
EBITDA	(32)	(59)	(74)	(94)	EBITDA	(10)A	(14)	(17)	(19)
Net interest (income) / expense	0	0	0	0	Net interest (income) / expense	0A	0	0	0
Other income / (expense)	(3)	(3)	0	0	Other income / (expense)	(3)A	0	0	0
Income taxes	0	0	0	0	Income taxes	0A	0	0	0
Net income - GAAP	(35)	(63)	(74)	(94)	Net income - GAAP	(14)A	(14)	(17)	(19)
Net income - recurring	(50)	(68)	(74)	(94)	Net income - recurring	(18)A	(14)	(17)	(19)
Diluted shares outstanding	3	28	32	33	Diluted shares outstanding	22A	30	30	30
EPS - excluding non-recurring	(14.87)	(2.41)	(2.28)	(2.82)	EPS - excluding non-recurring	(0.85)A	(0.45)	(0.55)	(0.63)
EPS - recurring	(14.87)	(2.41)	(2.28)	(2.82)	EPS - recurring	(0.85)A	(0.45)	(0.55)	(0.63)
Balance Sheet and Cash Flow Data	**FY13A**	**FY14E**	**FY15E**	**FY16E**	**Ratio Analysis**	**FY13A**	**FY14E**	**FY15E**	**FY16E**
Cash and cash equivalents	53	114	193	101	Sales growth	-	-	-	-
Accounts receivable	0	0	0	0	EBIT growth	-	84.2%	24.2%	27.6%
Inventories	-	-	-	-	EPS growth - recurring	-	(83.8%)	(5.2%)	23.8%
Other current assets	0	0	0	0					
Current assets	53	115	193	102	Gross margin	-	-	-	-
PP&E	1	2	2	2	EBIT margin	-	-	-	-
Total assets	55	117	196	104	EBITDA margin	-	-	-	-
					Tax rate	0.0%	0.0%	0.0%	0.0%
Total debt	-	-	-	-	Net margin	-	-	-	-
Total liabilities	4	5	5	5					
Shareholders' equity	51	112	191	99	Net Debt / EBITDA	-	-	-	-
					Net Debt / Capital (book)	-	-	-	-
Net income (including charges)	(35)	(63)	(74)	(94)					
D&A	0	0	0	0	Return on assets (ROA)	(70.0%)	(78.4%)	(47.2%)	(62.8%)
Change in working capital	0	0	0	0	Return on equity (ROE)	(74.2%)	(82.7%)	(48.7%)	(65.0%)
Other	1	1	2	2					
Cash flow from operations	(33)	(61)	(71)	(92)	Enterprise value / sales	-	-	-	-
					Enterprise value / EBITDA	NM	NM	NM	NM
Capex	0	0	0	0	Free cash flow yield	(22.0%)	(4.8%)	(4.9%)	(6.1%)
Free cash flow	(33)	(61)	(71)	(92)					
Cash flow from investing activities	0	0	0	0					
Cash flow from financing activities	0	122	150	0					
Dividends	-	-	-	-					
Dividend yield	-	-	-	-					

Source: Company reports and J.P. Morgan estimates.
Note: $ in millions (except per-share data).Fiscal year ends Dec

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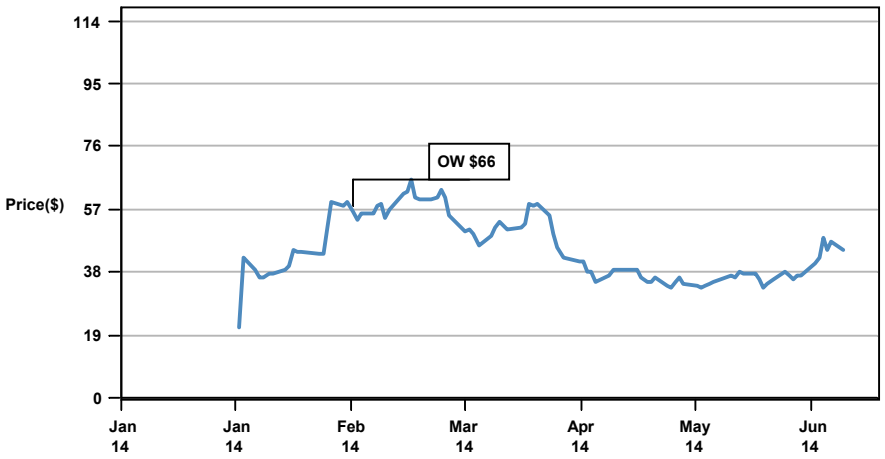
Ultragenyx (RARE, RARE US) Price Chart



Date	Rating	Share Price ($)	Price Target ($)
25-Feb-14	OW	58.01	66.00

Source: Bloomberg and J.P. Morgan; price data adjusted for stock splits and dividends.
Initiated coverage Feb 25, 2014.

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