Ultragenyx

Full SA-ER Phase 2 Data Shows Dose Dependent Efficacy, but Next Steps Remain Unclear

Overweight

RARE, RARE US
Price: $38.78

Price Target: $66.00

We are attending AAN, where last night RARE presented full data from the Phase 2 trial of Sialic acid extended-release (SA-ER) in Human GNE myopathy. Top line (qualitative) data was released in Dec 2013. The full data set reveals a separation from placebo and dose dependent effect on upper and lower extremity strength (though statistical significance was only reached in some measures), with a relatively clean safety profile. Of all RARE's programs, this is the one to which we have assigned the least amount of credit (30% P of success), but today's data detail has given us more incrementally confidence in this program. However, we continue to take a "wait and see" approach on SA-ER as we look forward to data from the higher dose (late 2014) and on regulatory clarity given the lack of precedent approvals in this indication. Overall, we continue to see RARE as well positioned with a broad and diverse portfolio of orphan disease assets and a highly regarded management team with a strong track record in the space. We think the stock's recent underperformance is largely a delayed reaction vs. the broader biotech downturn earlier in the year, and note that nothing has fundamentally changed with the story. We look forward to several key data readouts this year, which we believe could offer meaningful de-risking and value creation events. Reiterate Overweight.

- **SA-ER appears to stabilize progression of muscle weakness, showing stat sig benefits in upper limb strength and trends towards benefit in lower limbs.** Recall the this study evaluated SA-ER at 3g/day, 6g/day or placebo for 24 weeks, after which pts in the placebo arm were randomized/crossed over to receive 3g/day or 6g/day and treatment continued for an additional 24 weeks (n=46). The Upper Extremity Composite (UEC) muscle strength test showed a stat sig effect vs. placebo at 24 weeks in the 6g arm (+2.33 kg, 5.5%; p=0.04). At 48 weeks, the combined 6g cohort (with re-randomized placebo patients) was improved vs. the combined 3g cohort (+3.44 kg, 8.5%; p=0.0033). In the Lower Extremity Composite (LEC), trends towards efficacy were observed but were largely not stat sig. SA-ER was well tolerated, with no SAEs or dose-dependent treatment emergent AEs.

- **The consistency of effect post-inclusion of placebo patients corroborates efficacy signal.** We got a chance to speak with Dr. Kakkis who noted the continuation of trends from the 1st 24 weeks to the 2nd 24 weeks (post-inclusion of the placebo patients) in muscle strength bodes well as it corroborates the treatment effect (similar efficacy observed in "new" placebo pts). Patient-reported outcome data (GNEM-FAS) is supportive of the strength test data as well, suggesting that the 6g dose has a clinically meaningful effect on UEC.

Biotechnology

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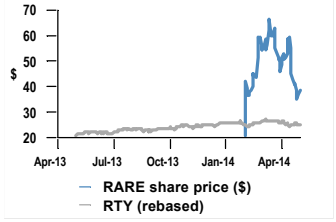
Price Performance



	YTD	1m	3m	12m
Abs	84.7%	-15.1%	84.7%	84.7%
Rel	86.8%	-12.9%	85.8%	65.8%

Ultragenyx Pharmaceutical (RARE;RARE US)

FYE Dec	2013A	2014E	2015E
EPS Reported ($)			
Q1 (Mar)	-	(0.35)	0.00
Q2 (Jun)	-	(0.44)	0.00
Q3 (Sep)	-	(0.53)	0.00
Q4 (Dec)	-	(0.61)	0.00
FY	(14.87)	(1.93)	(2.16)

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

Company Data	
Price ($)	38.78
Date Of Price	30 Apr 14
52-week Range ($)	69.77-34.12
Market Cap ($ mn)	145.21
Fiscal Year End	Dec
Shares O/S (mn)	4
Price Target ($)	66.00
Price Target End Date	31-Dec-14

See page 5 for analyst certification and important disclosures.

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- **More robust improvements observed in less advanced patients indicate early treatment initiation could lead to the greatest benefit.** In a pre-specified subgroup of patients who could walk >200m in the 6MWT at baseline (~70% of the study population), the treatment effect on the UEC was more robust (+4.69 kg, 9.6%; p<0.001). The abstract presenter, Dr. Argov (Hadassssah University, Israel) noted this 9-10% effect on muscle strength over 1 year (in both this subset and broader population) is encouraging, especially in the context of chronic treatment where a 9%/yr effect accumulated year-after year could lead to a significant cumulative benefit.

- **Dosing at a higher (12g/day) level is ongoing in an extension study, with data expected in late 2014.** Given the dose response observed in the initial portion of the study, Dr. Kakkis noted the importance of testing the higher dose to test the limits of the dose response. All patients from the initial period of the study opted to roll over into the open-label extension study. Ultragenyx is also working to develop pro-drugs of sialic acid (which could potentially have better penetration into muscle).

- **We are incrementally more encouraged by the full Phase 2 data but await clarification on next steps before assigning more value to the program.** RARE plans to meet with the FDA to discuss next steps for the program after they receive the higher dose data. Given the lack of a clear regulatory path in this indication, we remain on the sidelines until 1) we see data at the higher dose and 2) we get more clarity on what the FDA would want to see in a pivotal program.

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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	1Q14E	2Q14E	3Q14E	4Q14E
Revenues	0	0	0	0	Revenues	0	0	0	0
Cost of products sold	0	0	0	0	Cost of products sold	0	0	0	0
Gross profit	-	-	-	-	Gross profit	-	-	-	-
SG&A	(4)	(16)	(17)	(24)	SG&A	(3)	(4)	(4)	(5)
R&D	(28)	(42)	(57)	(70)	R&D	(8)	(10)	(12)	(13)
Operating income	(32)	(58)	(74)	(94)	Operating income	(11)	(13)	(16)	(18)
EBITDA	(32)	(58)	(74)	(94)	EBITDA	(11)	(13)	(16)	(18)
Net interest (income) / expense	0	0	0	0	Net interest (income) / expense	0	0	0	0
Other income / (expense)	(3)	0	0	0	Other income / (expense)	0	0	0	0
Income taxes	0	0	0	0	Income taxes	0	0	0	0
Net income - GAAP	(35)	(58)	(74)	(94)	Net income - GAAP	(11)	(13)	(16)	(18)
Net income - recurring	(50)	(58)	(74)	(94)	Net income - recurring	(11)	(13)	(16)	(18)
Diluted shares outstanding	3	30	34	35	Diluted shares outstanding	30	30	30	30
EPS - excluding non-recurring	(14.87)	(1.93)	(2.16)	(2.68)	EPS - excluding non-recurring	(0.35)	(0.44)	(0.53)	(0.61)
EPS - recurring	(14.87)	(1.93)	(2.16)	(2.68)	EPS - recurring	(0.35)	(0.44)	(0.53)	(0.61)

Balance Sheet and Cash Flow Data	FY13A	FY14E	FY15E	FY16E	Ratio Analysis	FY13A	FY14E	FY15E	FY16E
Cash and cash equivalents	53	119	198	106	Sales growth	-	-	-	-
Accounts receivable	0	0	0	0	EBIT growth	-	79.4%	27.5%	27.6%
Inventories	-	-	-	-	EPS growth - recurring	-	(87.0%)	11.5%	24.0%
Other current assets	0	0	0	0					
Current assets	53	119	198	107	Gross margin	-	-	-	-
PP&E	1	2	2	2	EBIT margin	-	-	-	-
Total assets	55	122	201	109	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	117	196	104	Net Debt / EBITDA	-	-	-	-
					Net Debt / Capital (book)	-	-	-	-
Net income (including charges)	(35)	(58)	(74)	(94)					
D&A	0	0	0	0	Return on assets (ROA)	(70.0%)	(65.4%)	(45.8%)	(60.8%)
Change in working capital	0	0	0	0	Return on equity (ROE)	(74.2%)	(68.8%)	(47.2%)	(62.9%)
Other	1	1	2	2					
Cash flow from operations	(33)	(56)	(71)	(92)	Enterprise value / sales	-	-	-	-
					Enterprise value / EBITDA	NM	NM	NM	NM
Capex	0	0	0	0	Free cash flow yield	(25.4%)	(4.8%)	(5.4%)	(6.7%)
Free cash flow	(33)	(56)	(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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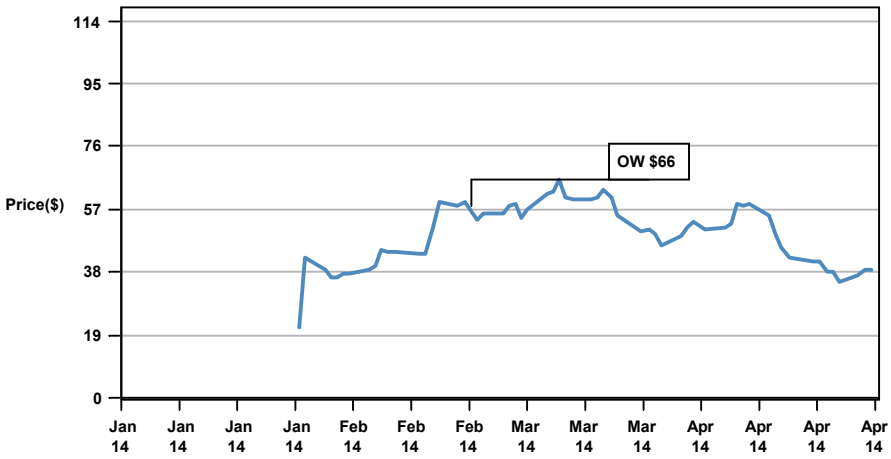
Ultragenyx (RARE, RARE US) Price Chart



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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IB clients*	78%	67%	60%

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