Ultragenyx (RARE)

Reports 3Q14 - Provides Updates on Clinical Programs

BUY

Price target $74.00

Price $44.71

EQUITY RESEARCH AMERICAS

Key Takeaway

RARE provided several clinical updates in their earnings release: 1) the FDA has agreed to RARE's proposed endpoints for phase 3 study of SA-ER, which will be initiated by mid-15; 2) RARE has amended their inclusion criteria for the phase 2 GLUT1-DS study to potentially accelerate enrollment; 3) Enrollment for the phase 2 KRN23 pediatric study was completed ahead of schedule

FDA agrees with RARE's proposed phase 3 design for SA-ER in HIBM; primary endpoint a major win. The phase 3 trial will be a 48-week randomized placebo controlled study, which we expect to enroll ~80-100 HIBM patients likely with less advanced disease at baseline. The primary endpoint will be upper-extremity composite strength (UEC) with secondary endpoints including the patient reported outcome GNEM-FAS scale. We view the acceptance of the UEC endpoint as a major positive for RARE given UEC and sub-scales of the GNEM-FAS were significantly improved in the phase 2 study while SA-ER did not have as much of an impact on the lower extremity composite. Additionally, the 6g dose that demonstrated a clinically meaningful advantage will be evaluated in this phase 3 study. We project peak WW adjusted sales of ~$65M.

Minor change to inclusion criteria for the ongoing phase 2 trial of THN in GLUT1 DS. RARE plans to expand the inclusion criteria of the ongoing study to enroll GLUT1-DS patients that experience absence seizures, in addition to other generalized/partial-onset seizures. Absence seizures are brief, sudden lapses of consciousness that are more common in children. While this will positively impact enrollment, timelines for both the THN trials in GLUT1-DS and FAOD were maintained with interim data expected in 2015. We project combined peak WW adjusted sales of ~$690M.

KRN23 pediatric study enrollment completed earlier than expected. The phase 2 study, which has enrolled ~30 pediatric XLH patients, is evaluating dose/regimen, safety and efficacy endpoints that include radiographic assessments, growth, strength and motor function. Interim data from this study is expected in 2015. We project WW peak adjusted KRN23 revenues of ~$295M.

Phase 3 study for rhGUS in MPS7 to initiate in 1Q15. While RARE continues to finalize the trial design with regulators, we expect primary endpoints to include uGAG, which was significantly improved in the phase 1/2 study. We project WW peak adjusted KRN23 revenues of ~$57M.

Valuation/Risks

Our $74 PT is DCF-based. Risks include clinical, regulatory, competitive, commercial.

USD	*Prev.*	2013A	*Prev.*	2014E	*Prev.*	2015E	*Prev.*	2016E
Rev. (MM)	--	0.0	--	0.0	--	0.0	--	0.0
EPS								
Mar	--	--	--	(0.63)A	--	--	--	--
Jun	--	--	--	(0.45)A	--	--	--	--
Sep	--	--	*(0.44)*	(0.50)A	--	--	--	--
Dec	--	--	*(0.44)*	(0.50)	--	--	--	--
FY Dec	--	(10.37)	*(1.74)*	(1.86)	*(2.30)*	(2.31)	--	(2.56)
FY P/E		NM		NM		NM		NM

Financial Summary	
Net Debt (MM):	$0.0
Cash & ST Invest. (MM):	$201.2
Market Data	
52 Week Range:	$69.77 - $32.02
Total Entprs. Value (MM):	$1,417.3
Market Cap. (MM):	$1,417.3
Insider Ownership:	31.3%
Institutional Ownership:	70.7%
Shares Out. (MM):	31.7
Float (MM):	21.3
Avg. Daily Vol.:	427,855

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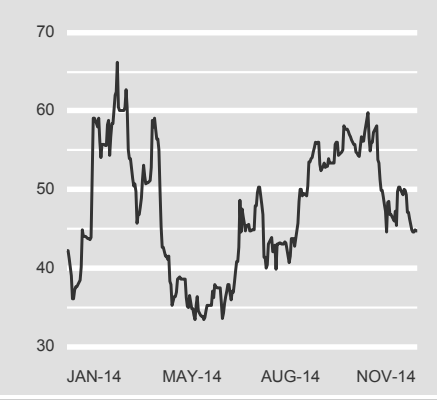
Price Performance



Untragenyx Pharmaceuticals

BUY: $74.00 Price Target

THE LONG VIEW

Scenarios

Target Investment Thesis

- For the following programs, we project the following launch years and peak WW probability adj. revenues:
  THN (LC-FAOD) – 2018/$328M
  THN (GLUT1 DS) – 2018/$363M
  rhGUS – 2017/$57M
  SA-ER – 2018/$65M
  KRN23 – 2018/$295M in revs to RARE
- We do not assign any value to **rhPPCA** (preclinical)
- DCF-based PT: $74

Upside Scenario

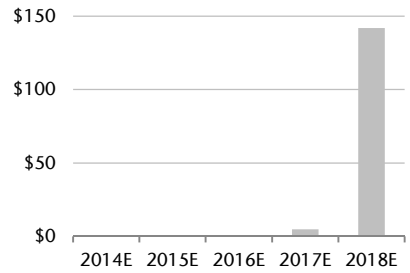
- KRN23 and rhGUS maintain their market share post patent expiration
- DCF-based PT: $101

Downside Scenario

- Triheptanoin fails to demonstrate clinically meaningful data for GLUT1 DS patients.
- SA-ER fails in a registration study
- DCF-based PT: $45

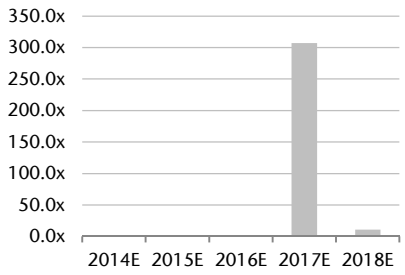
Long Term Analysis

Revenue (M)



Source: Factset & Jefferies

Enterprise Value (EV)/Revenue



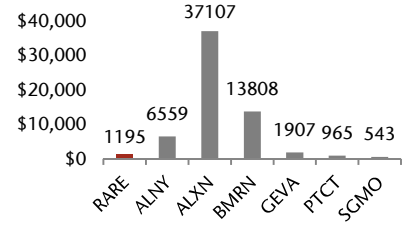
Source: Factset & Jefferies

Other Considerations

We believe there is significant opportunity for RARE to continue to in-license products and sustain long-term growth

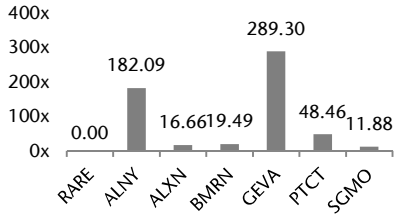
Peer Group

Enterprise Value (EV)



Source: Factset

Enterprise Value (EV)/Revenue



Source: Factset

Recommendation / Price Target

Ticker	Rec.	PT
RARE	**BUY**	**$74.00**
ALNY	NC	NC
ALXN	HOLD	$170.00
BMRN	BUY	$87.00
GEVA	NC	NC
PTCT	NC	NC
SGMO	BUY	$22.00

Catalysts

- SA-ER – initiate phase 3 trial – Mid '15
- rhGUS – initiate phase 3 trial – 1Q15
- THN – interim phase 2 data in LC-FAOD & GLUT1 DS – Mid-15
- KRN23 – interim phase 2 data in pediatric patients – 2H15

Company Description

Ultragenyx (RARE) is a development stage biotech company that is focused on developing and commercializing a broad pipeline of biologics (monoclonal antibody and enzyme replacement therapies) and small molecules (substrate replacement therapies) for the treatment of rare and ultra-rare serious metabolic genetic diseases. RARE has built its pipeline via in-licensing resulting in four clinical candidates for five indications: Triheptanoin/UX007 (THN) as an alternate source of energy for patients with long chain fatty acid oxidation disorders (LC-FAOD) and for patients with glucose transporter type 1 deficiency syndrome (Glut1 DS); KRN23 (in collaboration with Kyowa Hakko Kirin) for the treatment of X-linked hypophosphatemia (XLH); rhGUS for MPS VII (e.g. Sly Syndrome); and Sialic Acid Extended release for hereditary inclusion body myositis (HIBM).

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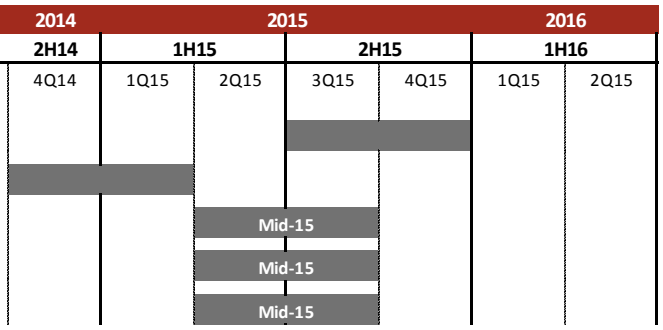
Upcoming catalysts for RARE

Drug	Indication	Phase	Catalyst
KRN23	XLH - Pediatric	II	Interim data
rhGUS	MPS VII	III	Initiate study
THN	GLUT1 Deficiency	II	Interim data
THN	FAOD	II	Interim data
SA-ER	HIBM	III	Initiate study



Source: Jefferies estimates, company data

RARE Income Statement: 2013A-2020E ($M)

(In Millions, except per share data)	2013A	1Q14A	2Q14A	3Q14A	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Revenues												
KRN23 (WW)	-	-	-	-	-	-	-	-	-	29.0	64.9	115.7
THN for FAOD	-	-	-	-	-	-	-	-	-	49.1	117.4	190.5
THN for GLUT1	-	-	-	-	-	-	-	-	-	47.5	113.4	202.1
rhGUS	-	-	-	-	-	-	-	-	4.9	10.2	20.1	32.4
SA-ER	-	-	-	-	-	-	-	-	-	6.0	19.4	33.7
Total Revenues	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**-**	**4.9**	**141.8**	**335.3**	**574.4**
Operating Expenses												
COGS	-	-	-	-	-	-	-	-	0.7	19.1	45.6	77.3
% of sales	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*15%*	*13%*	*14%*	*13%*
R&D	27.8	8.4	11.2	12.9	12.9	45.3	55.0	65.0	75.0	75.0	75.0	75.0
% of sales	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*1518%*	*53%*	*22%*	*13%*
SG&A	4.5	2.0	2.4	3.0	2.9	10.3	15.0	20.0	35.0	55.0	75.0	85.0
% of sales	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*N/M*	*709%*	*39%*	*22%*	*15%*
Total Operating expenses	**(32.3)**	**(10.3)**	**(13.7)**	**(15.8)**	**(15.8)**	**(55.6)**	**(70.0)**	**(85.0)**	**(110.7)**	**(149.1)**	**(195.6)**	**(237.3)**
Net Operating Income (Expense)	**(32.3)**	**(10.3)**	**(13.7)**	**(15.8)**	**(15.8)**	**(55.6)**	**(70.0)**	**(85.0)**	**(105.8)**	**(7.3)**	**139.7**	**337.1**
Other Income (Expense)												
Interest income	0.2	0.1	0.1	-	-	0.2	0.2	0.2	0.2	0.2	0.3	0.3
Interest expense	-	-	-	-	-	-	-	-	-	-	-	-
Other expense, net	(3.0)	(3.4)	(0.1)	(0.0)	(0.0)	(3.5)	(3.5)	(3.5)	(3.6)	(3.6)	(3.6)	(3.7)
Total Other Income (Expense)	**(2.8)**	**(3.3)**	**0.1**	**(0.0)**	**(0.0)**	**(3.2)**	**(3.2)**	**(3.3)**	**(3.3)**	**(3.3)**	**(3.4)**	**(3.4)**
Income before taxes	(35.1)	(13.6)	(13.6)	(15.8)	(15.8)	(58.8)	(73.2)	(88.3)	(109.1)	(10.7)	136.3	333.7
Taxes	-	-	-	-	-	-	-	-	-	-	(6.8)	(40.0)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5%*	*12%*
Net Income (Loss)	**(35.1)**	**(13.6)**	**(13.6)**	**(15.8)**	**(15.8)**	**(58.8)**	**(73.2)**	**(88.3)**	**(109.1)**	**(10.7)**	**129.5**	**293.7**
Basic EPS	(10.37)	(0.63)	(0.45)	(0.50)	(0.50)	(1.86)	(2.31)	(2.56)	(3.16)	(0.31)	3.72	8.42
Diluted EPS	(10.37)	(0.45)	(0.41)	(0.45)	(0.45)	(1.68)	(2.09)	(2.34)	(2.88)	(0.28)	3.40	7.69
Shares outstanding (Basic)	3.4	21.6	30.1	31.7	31.7	31.7	31.8	34.5	34.6	34.7	34.8	34.9
Shares outstanding (Diluted)	3.4	30.1	33.0	35.0	35.0	35.0	35.1	37.8	37.9	38.0	38.1	38.2

Source: Jefferies estimates, company data

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Company Description

Ultragenyx Pharmaceutical, Inc. is a clinical-stage biotechnology company. The company is focused on the identification, acquisition, development, and commercialization of novel products for the treatment of rare and ultra-rare diseases, with an initial focus on serious, debilitating metabolic genetic diseases. Ultragenyx Pharmaceutical was founded by Emil D. Kakkis on April 22, 2010 and is headquartered in Novato, CA.

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Risk which may impede the achievement of our Price Target

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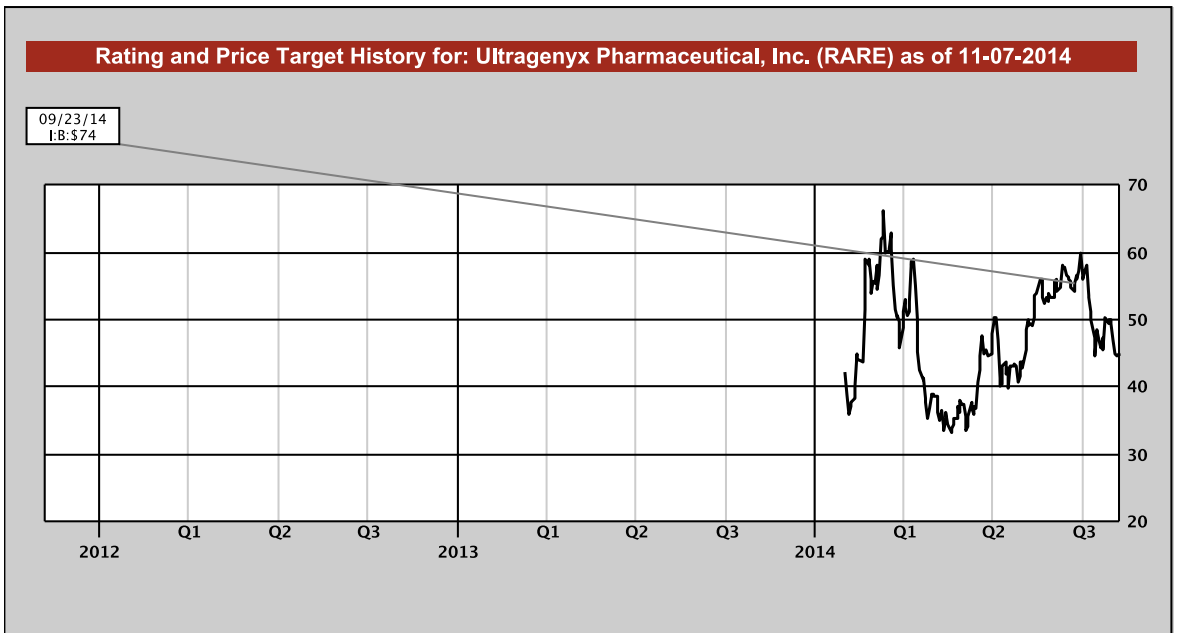
Other Companies Mentioned in This Report

- Alexion Pharmaceuticals, Inc. (ALXN: $193.81, HOLD)
- BioMarin Pharmaceutical Inc. (BMRN: $83.91, BUY)
- Sangamo Biosciences, Inc. (SGMO: $11.32, BUY)
- Ultragenyx Pharmaceutical, Inc. (RARE: $44.71, BUY)



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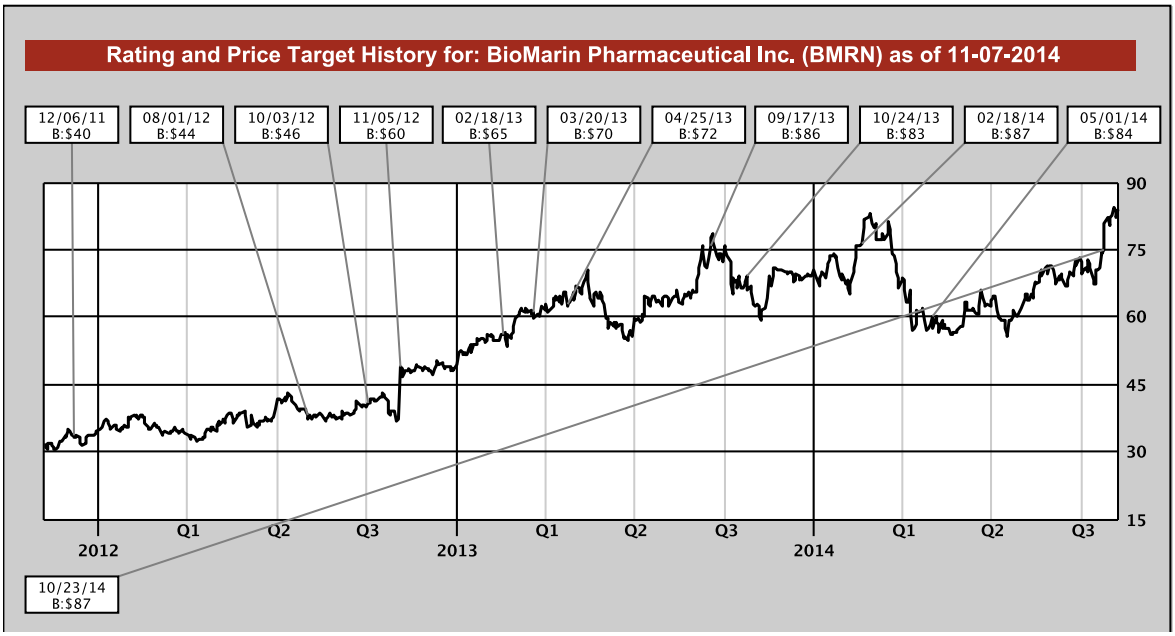

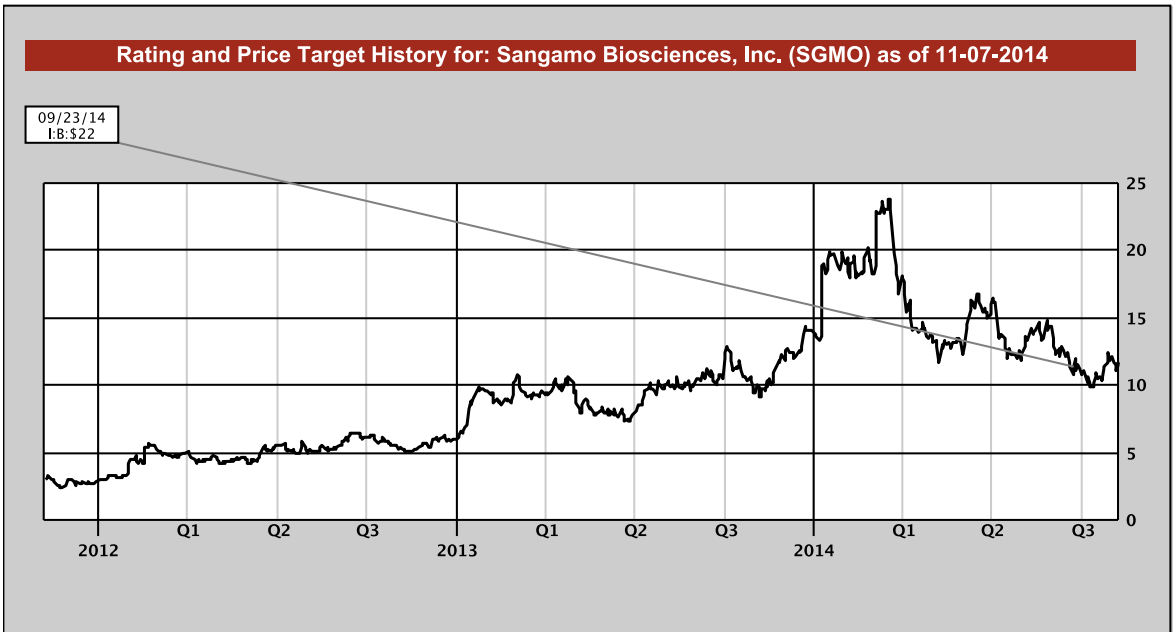

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Rating	Count	Percent	IB Serv./Past 12 Mos. Count	IB Serv./Past 12 Mos. Percent
BUY	1010	52.09%	265	26.24%
HOLD	790	40.74%	143	18.10%
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