# Radius Health (RDUS)

# Positive ACTIVExtend Data for ABL; NDA/ MAA Filings on Track for 2H15; PT Raised

#### **Key Takeaway**

ACTIVExtend 25-mo data for ABL shows sustained tx effect vs. placebo. Importantly, on major osteoporotic fracture reduction, ABL is statistically superior vs. competitor Forteo (53% reduction). Although Forteo (\$300M in 1Q15 sales) goes generic in 2019, we view market entry of additional/better anabolic agents will likely help expand currently treated pt population (~20% of eligible).

RDUS reported ACTIVExtend 25-mo data for abaloparatide-SC (ABL) in osteoporosis, demonstrating sustained tx effect in previously ABL-pts; NDA/ MAA filing on track for in 2H15. ACTIVExtend (n=1139) is a 6-mo extension study from Ph3 ACTIVE trial (18-mo tx with ABL, placebo or Forteo, n=2118), where pts on ABL and placebo (PBO) were rolled over & maintained on alendronate for 6-mo. Primary endpoint was safety, with secondary endpoints of vertebral/non-vertebral fracture rate.

In Charts 1 and 2, ABL tx led to continued reductions in new vertebral, nonvertebral, clinical & major osteoporotic fractures (vs. PBO); and continued increases in BMD (vs. BL) at 25-mo from 18-mo. Adverse events were consistent with previous clinical experience.

For osteoporotic fracture (first sign of bone loss), exploratory analysis shows ABL tx led to 53% reduction in major osteoporotic fracture vs. LLY's Forteo (p=0.0437) at 18-mo - a differentiating point. In 18-mo ACTIVE trial, ABL tx led to 67% reduction in major osteoporotic fracture vs. PBO (p=0.0014) and 53% reduction vs. competitor Eli Lilly's (LLY, Buy) Forteo (TP, teriparatide; p=0.0437). Major osteoporotic fracture is associated with high morbidity (wrist/vertebral fracture more common in younger pts vs. hip fracture in older pts). Another differentiating point is against PBO, ABL was statistically superior in non-vertebral & clinical fracture reductions, but Forteo did not reach statistical significance in ACTIVE trial (Chart 1). Amgen (AMGN, Buy) notes ~400K pts out of estimated 2.1M eligible high-risk PMO pts with history of fracture in U.S. (a potential market for anabolic agents) are currently diagnosed & treated; ~500K diagnosed, but untreated. Thus, we view market entry of additional/better anabolic agents will likely help expand # of treated pts.

#### Valuation/Risks

Our \$66 PT (was \$56) is based on an NPV analysis of abaloparatide-SC & RAD1901. Risks include: (1) regulatory delays/failure & slow commercial uptake and/or competition of abaloparatide-SC, and (2) development delay/failure of RAD1901.

USD	Prev.	2014A	Prev.	2015E	Prev.	2016E	Prev.	2017E
Rev. (MM)		0.0		0.0		90.0	99.8	113.3
EPS								
Mar		(50.45)		(0.47)A				
Jun		(2.22)		(0.47)				
Sep		(0.59)		(0.45)				
Dec		(0.55)		(0.46)				
FY Dec		(4.04)		(1.85)		(0.42)	(1.13)	(0.84)
EPS: RDUS com	pleted its IP	O in 2Q14						

#### BUY

Price target \$66.00 (from \$56.00) Price \$51.73

Financial Summary	
Book Value (MM):	\$206.9
Book Value/Share:	\$5.70
Net Debt (MM):	(\$234.2)
Long-Term Debt (MM):	\$0.0
Cash/Share:	\$6.45
Cash (MM):	\$234.2
Market Data	
Market Data	
<b>Market Data</b> 52 Week Range:	\$52.50 - \$8.00
	\$52.50 - \$8.00 \$1,643.6
52 Week Range:	
52 Week Range: Total Entprs. Value (MM):	\$1,643.6
52 Week Range: Total Entprs. Value (MM): Market Cap. (MM):	\$1,643.6 \$1,877.8
52 Week Range: Total Entprs. Value (MM): Market Cap. (MM): Shares Out. (MM):	\$1,643.6 \$1,877.8 36.3

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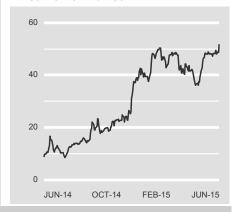
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#### **Price Performance**



Target | Estimate Change

June 18, 2015

Upping our PT to \$66 (from \$56) on ~15% increase in our abaloparatide sales estimates to ~\$770M in 2027 (vs. \$670M previously) using a ~9% discount rate (vs. 9.7% previously). Our abaloparatide sales estimates assume annual treatment cost starting at ~\$24K per patient (vs. \$17K previously) following a series of price increases for Forteo, the most of which took effect 5/29/15, and 60% peak penetration (vs. 65% previously). Recent WAC increases for Forteo in the U.S. include ~15% on 05/29/2015 (\$2,020.80/mo; ~\$24K/yr); ~14% on 12/04/2014 (\$1,758.20/mo; \$~21K/yr); ~9% on 07/02/2014 (\$1,545.00/mo; ~\$19K/yr); and 12/18/2013 (\$1,417.40/mo; \$~17K/yr). For 2013 and 2014, total Forteo sales were \$1,245M (+8% y/y) and \$1,322M (+6% y/y), respectively.

Based on NPV analysis, our PT of \$66 includes ~\$52 for abaloparatide (vs. \$42 prior), and ~\$14 for RAD1901 (unchanged) using a ~9% annual discount rate (vs. 9.7% prior).

# Chart 1: ACTIVExtend & ACTIVE Fracture Reduction Data for Abaloparatide in Osteoporosis

Percent Change in A	ABL vs. Forteo	Forteo vs. Placebo		
	ACTIVE at 18-mo	ACTIVExtend at 25-mo*	ACTIVE at 18-mo	ACTIVE at 18-mo
New vertebral fracture reduction	86% (p<0.0001)	87% (p<0.0001)	N/A	80% (p<0.0001)
Non-vertebral fracture reduction	43% (p=0.0489)	52% (p=0.0168)	N/A	Not stat. significant
Clinical fracture reduction	45% (p=0.0112)	48% (p=0.0139)	N/A	Not stat. significant
Major osteoporotic fracture reduction	67% (p=0.0014)	58% (p=0.0122)	53% (p=0.0437)	N/A

<sup>\*</sup>For ACTIVExtend portion (n=1139), all patients received alendronate following the 18-month ACTIVE portion. In ACTIVE portion, abaloparatide-SC (n=690), placebo (n=711) & Forteo (n=717)

Source: Company reports, and Jefferies

#### Chart 2: ACTIVExtend & ACTIVE BMD Data for Abaloparatide in Osteoporosis

Percent Change in Aba	Forteo vs. BL		
	ACTIVE at 18-mo**	ACTIVE at 18-mo**	
BMD increase at spine	9.2%	12.8%	9.1%
BMD increase at femoral neck (1)	2.9%	4.5%	2.3%
BMD increase at total hip (2)	3.4%	5.5%	2.8%

<sup>\*\*</sup>p<0.0001 for ABL and Forteo vs. placebo at 18 mo

Source: Company reports, and Jefferies

<sup>(1)</sup> p=0.0016 for ABL vs. Forteo at 18 mo

<sup>(2)</sup> p=0.0003 for ABL vs. Forteo at 18 mo

Target | Estimate Change

June 18, 2015

# Radius Health (RDUS) Income Statement

(\$ in thousands except per share)

	2013	1Q14	2Q14	3Q14	4Q14	2014	1Q15	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenues																					
Abaloparatide-SC for PMO (U.S.)												-	68,253	179,647	266,931	328,278	353,889	403,568	421,870	441,002	461,002
Growth y/y														163%	49%	23%	8%	14%	5%	5%	5%
Growth q/q																					
Royalty for abaloparatide-SC for PMO (EU)													-	11,303	29,160	42,470	51,197	54,098	60,471	61,962	63,489
Growth y/y															158%	46% 65.650	21%	6%	12% 440.138	2%	2%
RAD1901 for ER+ mBC (U.S.)																05,650	174,473 166%	305,621 75%	440,138 44%	533,169	586,824 10%
Growth y/y Royalty for RAD1901 for ER+ mBC (EU)																_	13,261	34,546	56,942	80,381	95,443
Growth y/y																	13,201	161%	65%	41%	19%
Other revenues												90,000	45,000			180,000					
Total Revenues	_	-	-	-	-	-	-	_	-	-	-	90,000	113,253	190,949	296,091	616,398	592.820	797.833	979.421	1,116,514	1,206,757
% growth y/y														68.6%	55.1%	108.2%	-3.8%	34.6%	22.8%	14.0%	8.1%
Expenses																					
Cost of Goods Sold		-	-	-	-	-	-	-	-	-	-	-	12,285	26,947	37,370	50,554	65,198	83,026	103,258	115,979	124,481
% gross margin (Including royalties to Ipsen & Eisai)													82.0%	85.0%	86.0%	87.2%	87.7%	88.3%	88.0%	88.1%	88.1%
R&D	60,536	9,717	10,618	13,817	11,567	45,719	11,559	10,500	10,000	9,088	41,147	47,319	55,363	66,436	73,080	78,926	85,240	92,059	99,424	107,378	115,968
% growth y/y	10.1%					-24.5%					-10.0%	15.0%	17.0%	20.0%	10.0%	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%
% of total revenues														34.8%	24.7%	12.8%	14.4%	11.5%	10.2%	9.6%	9.6%
SG&A	6,829	2,139	3,070	2,836	5,629	13,674	4,756	5,800	5,900	6,927	23,383	44,427	64,419	70,861	88,576	101,862	112,049	121,013	130,694	141,149	152,441
% growth y/y	-27.9%					100.2%					71.0%	90.0%	45.0%	10.0%	25.0%	15.0%	10.0%	8.0%	8.0%	8.0%	8.0%
% of total revenues													56.9%	37.1%	29.9%	16.5%	18.9%	15.2%	13.3%	12.6%	12.6%
Restructuring cost																					
Total Expenses	67,365	11.856	13.688	16,653	17,196	59,393	16,315	16,300	15,900	16,015	64,530	91.746	132,068	164,244	199,026	231,343	262,486	296,098	333,376	364,506	392,890
Income (loss) from Operations (EBIT)	(67,365)	(11,856)	(13,688)	(16,653)	(17,196)	(59,393)	(16,315)	(16,300)	(15,900)	(16,015)	(64,530)	(1,746)	(18,815)	26,705	97,065	385,055	330,333	501,736	646,045	752,008	813,867
% growth y/y		, , ,	, , ,			` '				, , ,	, , ,	, , ,	, , ,			296.7%	-14.2%	51.9%	28.8%	16.4%	8.2%
Operating margin															32.8%	62.5%	55.7%	62.9%	66.0%	67.4%	67.4%
Other Income (Expense), Net	6,675	(2,632)	1,079	(767)	(766)	(3,086)	(742)	(750)	(750)	(758)	(3,000)	(13,800)	(12,600)	(6,300)	500	1,000	2.000	3,000	4.000	5,000	6.000
Earnings (Loss) Before Taxes	(60,690)	(14,488)	(12,609)	(17,420)	(17,962)	(62,479)	(17,057)	(17,050)	(16,650)	(16,773)	(67,530)	(15,546)	(31,415)	20,405	97,565	386,055	332,333	504,736	650,045	757,008	819,867
Provision for Taxes	_	, , ,	,,,,,,	` ′ ′	, , ,	_	, , , , ,	, ,,	, ,,,,,,,,	( -, -,	_		_	_	_	19,303	33,233	75,710	130,009	189,252	245,960
Tax Rate																5.0%	10.0%	15.0%	20.0%	25.0%	30.0%
Net Income (Loss)	(60.690)	(14.488)	(12.609)	(17.420)	(17.962)	(62,479)	(17.057)	(17.050)	(16.650)	(16.773)	(67.530)	(15.546)	(31.415)	20.405	97.565	366.752	299.100	429.025	520.036	567.756	573,907
Extinguishment of preferred stock																					
Accretion of preferred stock	(17,471)	(4,969)	(4,031)			(9,000)															
Earnings to preferred stockholders	(,,	( .,= == ,	( .,===,			(0,000)															
Unrealized loss from marketable securities							62				62										
Net Income (Loss) to Common Stockholders	(78.161)	(19.457)	(16.640)	(17.420)	(17.962)	(71.479)	(17.057)	(17.050)	(16.650)	(16.773)	(67.530)	(15.546)	(31.415)	20.405	97.565	366.752	299.100	429.025	520.036	567.756	573.907
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EPS (LPS) - Basic	(203.91)	(50.45)	(2.22)	(0.59)	(0.55)	(4.04)	(0.47)	(0.47)	(0.45)	(0.46)	(1.85)	(0.42)	(0.84)	0.54	2.55	9.48	7.65	10.87	13.04	14.10	14.11
EPS (LPS) - Diluted	(203.91)	(50.45)	(2.22)		(0.55)	(4.04)	(0.47)	(0.47)	(0.45)	(0.46)	(1.85)	(0.42)	(0.84)	0.54	2.25	8.38	6.77	9.61	11.54	12.47	12.48
% growth y/y (diluted)	(/	(,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	,,	, , ,	,0.00/	,,	, ,	,,,,,	, ,	, , , , ,	,=,	,,	(0.0.7)			272.2%	-19.3%	42.0%	20.0%	8.1%	0.1%
Shares - Basic	383	386	7,500	29,746	32,678	17,699	36,269	36,450	36,633	36,816	36,542	37,184	37,556	37,931	38,311	38,694	39,081	39,471	39,866	40,265	40,667
Shares - Diluted	383	386	7,500	29,746	32,678	17,699	36,269	36,450	36,633	36,816	36,542	37,184	37,556	37,931	43,311	43,744	44,181	44,623	45,069	45,520	45,975
Shares bridged	363	300	7,500	23,140	32,076	17,039	30,209	30,430	20,023	30,010	30,342	37,184	37,330	37,531	43,311	43,744	44,101	44,023	43,009	43,320	43,373
Cash, Cash Equivalents & Investments	12.303	29.558	79.021	68.514	105,276	105,276	234,174	217,124	200,474	183,701	183,701	168,155	136,740	157,146	254,711	621,463	920.563	1.349.588	1.869.624	2,437,380	3.011.287
easily easil equivalents at investments	12,505	23,330	13,021	: 00,514	103,270	103,270	-37,1/4	-11,144	200,774	203,701	103,701	100,133	130,740	137,140	234,711	321,703	320,303	1,343,300	1,505,024	2,437,330	3,311,207

Source: Jefferies and Company financials

Target | Estimate Change

June 18, 2015

# **Company Description**

Radius Health, Inc. is a biopharmaceutical company focused on developing therapies for osteoporosis and other endocrine diseases. The company's lead product is abaloparatide-SC (BA058), a novel synthetic peptide analog of parathyroid hormone-related protein (PTHrP), with topline data readout for ongoing Phase 3 for osteoporosis released on 12/22/14 and potential NDA filing in 2H15. Additional pipeline products include a transdermal patch of abaloparatide, abaloparatide-TD; RAD1901, an oral selective estrogen receptor down-regulator/degrader (SERD) for the treatment of breast cancer brain metastases and vasomotor symptoms; and RAD140, a nonsteroidal selective androgen receptor modulator. Radius was founded in 2003 and is headquartered in Cambridge, Massachusetts.

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# RDUS Target | Estimate Change June 18, 2015

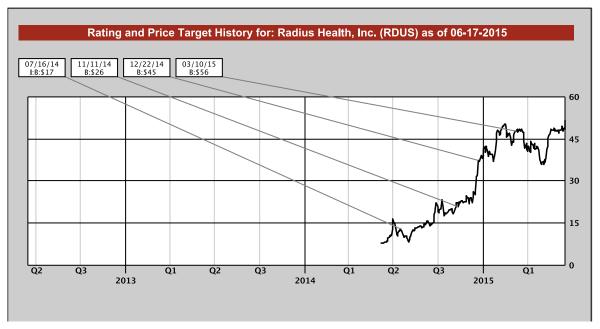
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#### **Other Companies Mentioned in This Report**

- ACADIA Pharmaceuticals Inc. (ACAD: \$40.16, BUY)
- Amgen, Inc. (AMGN: \$155.65, BUY)
- Eli Lilly & Co. (LLY: \$83.53, BUY)
- Neurocrine Biosciences (NBIX: \$45.56, BUY)
- Pfizer, Inc. (PFE: \$33.98, BUY)Tesaro, Inc. (TSRO: \$56.33, BUY)



# **Distribution of Ratings**

			IB Serv./Past 12 Mos.				
Rating	Count	Percent	Count	Percent			
BUY	1083	51.99%	299	27.61%			
HOLD	834	40.04%	160	19.18%			
UNDERPERFORM	166	7.97%	13	7.83%			

Target | Estimate Change

June 18, 2015

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