

## US Equity Research

13 January 2015

## BUY

unchanged

PRICE TARGET US\$70.00

unchanged

Price (12-Jan) US\$38.90

Ticker RDUS-NASDAQ

52-Week Range (US\$): 7.46 - 44.67  
 Avg Daily Vol (M) : 175.3  
 Shares Out. (M) : 29.7  
 Market Cap (US\$M): 1,157

FYE Dec	2013A	2014E	2015E	2016E
Revenue (US\$M)	0.0	0.0	0.0	82.1
EPS Adj&Dil (US\$)	(3.97)	(54.05)	(3.06)	(1.52)

Quarterly Revenue	Q1	Q2	Q3	Q4
2013A	-	-	-	-
2014E	0.0A	0.0A	0.0A	0.0
2015E	0.0	0.0	0.0	0.0
2016E	-	-	-	-

Quarterly EPS Adj&Dil	Q1	Q2	Q3	Q4
2013A	-	-	-	-
2014E	(50.45)A	(2.22)A	(0.59)A	(0.79)
2015E	(0.68)	(0.88)	(0.75)	(0.75)
2016E	-	-	-	-



Radius is a biotechnology company focused on drugs for endocrine disorders, including osteoporosis.

John Newman, PhD | Canaccord Genuity Inc. (US) | JNewman@canaccordgenuity.com | 212.389.8042

Kevin Dai, PharmD, BCOP | Canaccord Genuity Inc. (US) | kdai@canaccordgenuity.com | 212.389.8043

## Company Update

## Phase 3 detail shows significant benefit for abaloparatide vs. Forteo

## Large numerical fracture rate benefit for abaloparatide vs. Forteo at non-vertebral sites

Abaloparatide showed a 43% fracture reduction vs placebo at non-vertebral sites, compared to only a 28% reduction for Forteo vs placebo, a significant numerical difference, strongly favoring abaloparatide in our view, which should move shares higher. Abaloparatide also showed a numerically better hazard ratio of 0.57 for non-vertebral fracture reduction vs. placebo ( $p=0.0489$ ) compared to 0.72 for Forteo vs. placebo, where Forteo did not reach statistical significance. We believe the additional detailed data disclosure strengthen commercial positioning for abaloparatide vs. Forteo.

## Statistically significant difference in time to first fracture for abaloparatide

Abaloparatide prolonged time to first non-vertebral clinical fracture vs placebo in a statistically significant fashion, and curves show an almost immediate separation from placebo and Forteo. Importantly, the Forteo arm does not separate from placebo until ~420 days on treatment. Longer time to first non-vertebral fracture should add support to the strong fracture reduction seen for abaloparatide versus placebo, increasing the chances of FDA approval in our view.

## Lower numerical wrist fracture rate for abaloparatide vs. Forteo

Interestingly, abaloparatide showed a statistically significantly lower wrist fracture rate versus Forteo (0.5% vs. 2.0%,  $p=0.0149$ ), which we also view as a significant positive. Although neither abaloparatide nor Forteo showed a statistically significant reduction versus placebo (1.5%), we believe the results favor abaloparatide, and further suggest a commercial advantage over Forteo.

## More stringent statistical analysis still produces robust results

Radius performed a more stringent statistical analysis for Phase 3 ACTIVE data for abaloparatide, which produced equally robust results for all endpoints, in our view. Abaloparatide showed an 86% reduction in vertebral fracture versus placebo ( $p<0.0001$ ), vs. 83% for the original analysis, and Forteo showed an 80% reduction ( $p<0.0001$ ) vs. 78% for the original analysis. FDA comments received on January 8, 2015 suggested Radius exclude worsening vertebral fracture and include only new vertebral fracture. Importantly, FDA's recommendations for the secondary endpoint of non-vertebral fractures were consistent with Radius' analysis, which excluded sternal and patella fractures.

**Figure 1: ACTIVE trial - primary and secondary endpoints**

Site	abaloparatide			Forteo			placebo
	% fracture	% reduction	p	% fracture	% reduction	p	% fracture
Vertebral (Primary)	0.72%	83%	<0.0001	0.98%	78%	<0.0001	4.36%
Non-vertebral (Secondary)		43%	stat sig		28%	-	
Adjudicated clinical fracture (Secondary) (includes both vertebral and non-vertebral fracture)		45%	stat sig		29%	-	
	abaloparatide			Forteo			placebo
	% fracture	HR	p	% fracture	HR	p	% fracture
Time to first Non-vertebral fracture	2.7%	0.57	0.0489	3.3%	0.72	NS	5%

Source: Company report

**Figure 2: ACTIVE trial - FDA requested exclusions**

Exclude worsening vertebral fracture - new fracture only							
	abaloparatide			Forteo			placebo
	% fracture	% reduction	p	% fracture	% reduction	p	% fracture
Vertebral	0.58%	86%	<0.0001	0.84%	80%	<0.0001	4.22%

Source: Company report

**Figure 3: ACTIVE trial - wrist fractures**

	abaloparatide			Forteo		placebo
	% fracture	p		% fracture	p vs. placebo	% fracture
		vs. placebo	vs. Forteo			
<b>Wrist</b>	0.5%	NS	0.0149	2.0%	NS	2%

Source: Company report

**Figure 4: ACTIVE trial - abaloparatide improves BMD**

Mean Percent Change In Bone Mineral Density (BMD) From Baseline (ANCOVA approach)

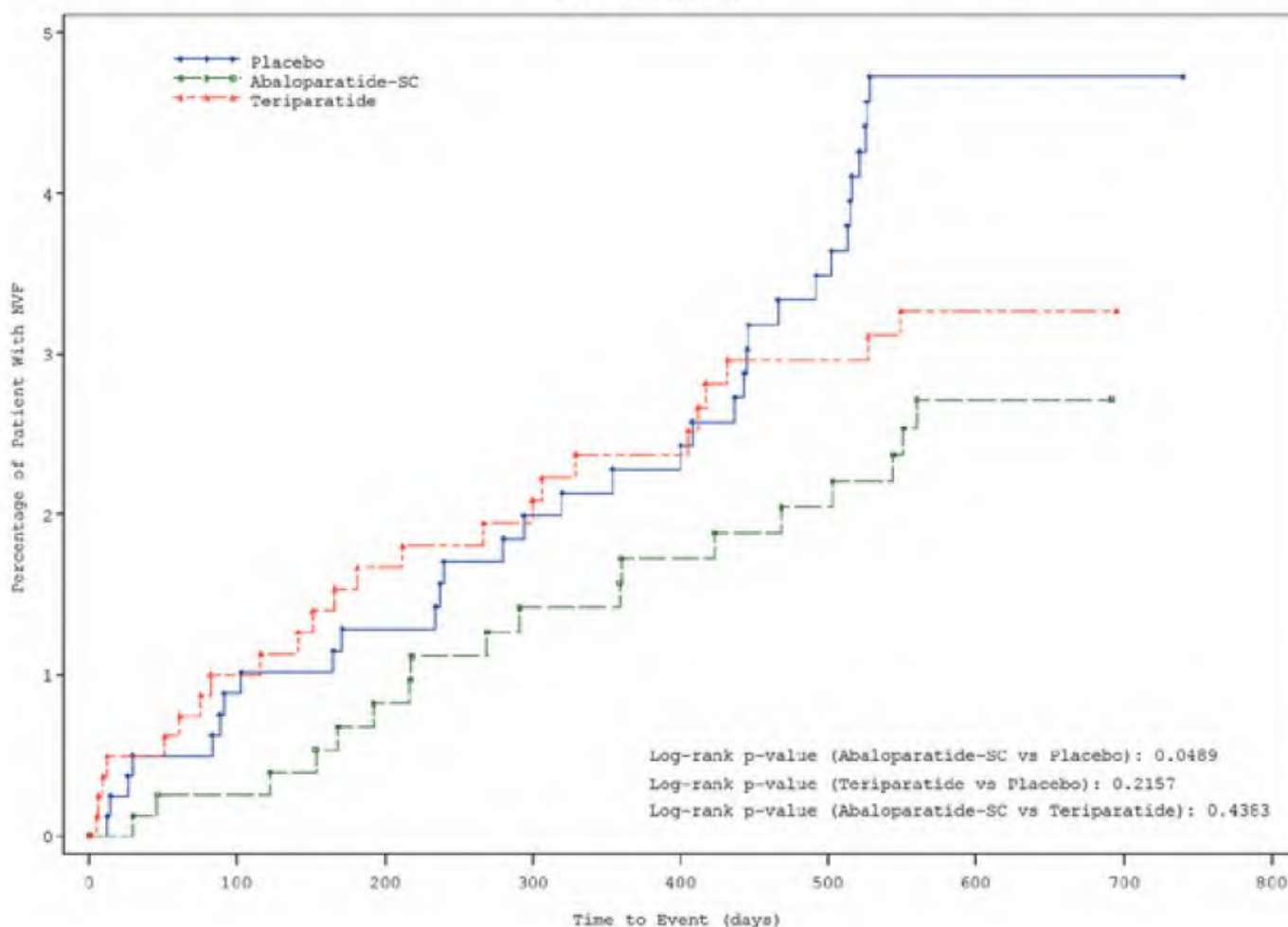
	Lumbar Spine			Total Hip			Femoral Neck		
	6 mo	12 mo	18 mo	6 mo	12 mo	18 mo	6 mo	12 mo	18 mo
Placebo	0.55%	0.39%	0.48%	0.29%	0.10%	-0.08%	-0.12%	-0.37%	-0.44%
abaloparatide-SC	5.90%**	8.19%***	9.20%*	2.07%**	2.87%**	3.44%****	1.54%**	2.21%**	2.90%*****
teriparatide	4.84%*	7.40%*	9.12%*	1.33%*	2.03%*	2.81%*	0.80%*	1.41%*	2.26%*

\* vs. placebo  $p < 0.0001$ \*\* vs. teriparatide  $p < 0.0001$ \*\*\* vs. placebo  $p < 0.0001$  AND vs. teriparatide  $p = 0.0087$ \*\*\*\* vs. placebo  $p < 0.0001$  AND vs. teriparatide  $p = 0.0003$ \*\*\*\*\* vs. placebo  $p < 0.0001$  AND vs. teriparatide  $p = 0.0016$ 

Source: Company report

**Figure 5: ACTIVE trial – Abaloparatide demonstrates statistical significant difference vs. placebo in time to first incident non-vertebral fracture**

Kaplan Meier Curve of Time to First Incident Non-Vertebral Fractures (NVF) by Treatment Group (ITT Population)



Source: Company report

Figure 6: RDUS valuation

Product	Peak Sales (\$MM)	Year	NPV at launch	Estimated launch	Time to launch	Probability Adjustment	Current Value (\$MM)	Scenario probability	Value / Share (NPV)	Value / Share (EV/Sales)
<b>abaloparatide</b>										
US	\$822	2022	\$1,364	6/1/2016	1.4	85%	\$951	100%	\$33	\$47
Ex-US - co-promote	\$346	2021	\$429	1/1/2017	2.0	85%	\$267	50%	\$5	\$11
Ex-US - royalty	\$346	2021	\$201	1/1/2017	2.0	85%	\$137	50%	\$2	\$11
<b>Total abaloparatide</b>							<b>\$1,218</b>		<b>\$40</b>	<b>\$69</b>
<b>RAD-1901</b>										
US	\$467	2023	\$670			35%	\$234		\$8	\$10
Ex-US	\$427	2023	\$188			35%	\$66		\$0	\$9
<b>Total RAD-1901</b>							<b>\$300</b>		<b>\$8</b>	<b>\$19</b>
<b>Total Product Value</b>							<b>\$1,218</b>		<b>\$48</b>	<b>\$87</b>
Cash							70		\$2	\$2
<b>Total Equity Value</b>							<b>1,288</b>		<b>\$50</b>	<b>\$90</b>
Shares Outstanding (MM)							29			
									Average	<b>\$70</b>
Risk-Free Rate	3.0%									
Beta	1.8									
Risk Premium	5%									
Discount Rate	12%									
EV/Sales	4.25									

Source: Canaccord Genuity estimates

Figure 7: RDUS income statement

Revenues	2013A	1Q14A	2Q14A	3Q14A	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
abaloparatide - US								82,120	239,867	357,419	465,944	583,042
abaloparatide - Ex-US								-	90,548	204,751	251,503	298,717
<b>Total</b>								<b>82,120</b>	<b>330,415</b>	<b>562,170</b>	<b>717,447</b>	<b>881,759</b>
Income Statement	2013A	1Q14A	2Q14A	3Q14A	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Total Revenue</b>	-	-	-	-	-	-	-	82,120	264,315	457,747	594,210	738,375
COGS	-	-	-	-	-	-	-	16,424	52,863	91,549	118,842	147,675
<b>Gross Profit</b>	-	-	-	-	-	-	-	65,696	211,452	366,198	475,368	590,700
<b>Operating Expenses</b>												
Research and development	60,536	9,717	10,618	13,817	14,926	49,078	74,464	59,354	55,796	65,122	84,196	117,620
abaloparatide-SC	45,977	8,107	9,728	10,132	12,158	40,126	27,052	18,937	13,256	13,256	13,256	13,256
abaloparatide-TD	11,459	185	278	523	785	1,770	31,380	21,966	15,376	10,763	7,534	5,274
RAD1901	-	-	-	1,027	1,000	2,027	12,100	14,520	23,232	37,171	59,474	95,158
RAD140	-	-	-	-	-	-	-	-	-	-	-	-
other	3,100	1,425	1,710	819	983	4,937	3,932	3,932	3,932	3,932	3,932	3,932
General and administrative	6,829	2,139	3,070	2,836	2,700	10,745	13,200	57,484	85,902	102,993	133,697	166,134
<b>Total Operating Expense</b>	<b>67,365</b>	<b>11,856</b>	<b>13,688</b>	<b>16,653</b>	<b>17,626</b>	<b>59,823</b>	<b>87,664</b>	<b>116,838</b>	<b>141,698</b>	<b>168,115</b>	<b>217,893</b>	<b>283,754</b>
EBITDA												
<b>Operating income</b>	<b>(67,365)</b>	<b>(11,856)</b>	<b>(13,688)</b>	<b>(16,653)</b>	<b>(17,626)</b>	<b>(59,823)</b>	<b>(87,664)</b>	<b>(51,142)</b>	<b>69,754</b>	<b>198,083</b>	<b>257,475</b>	<b>306,946</b>
Other income (expense), net	9,085	(2,233)	1,727	(802)	(802)	(2,110)	(5,824)	(2,110)	(5,824)	(2,110)	(5,824)	(2,110)
Loss on retirement of note payable			(203)									
Interest (expense) income, net	(2,410)	(399)	(445)	24	24	(796)	(1,544)	(796)	(1,544)	(796)	(1,544)	(796)
Accretion of preferred stock		(4,969)	(4,031)									
<b>Pre-tax income (GAAP)</b>	<b>(60,690)</b>	<b>(19,457)</b>	<b>(16,640)</b>	<b>(17,431)</b>	<b>(18,404)</b>	<b>(71,932)</b>	<b>(95,032)</b>	<b>(54,048)</b>	<b>62,386</b>	<b>195,177</b>	<b>250,107</b>	<b>304,040</b>
<b>Pre-tax income (non-GAAP)</b>												
Taxes (GAAP)	-	-	-	-	-	-	-	-	23,083	72,215	92,540	112,495
Tax rate (GAAP)	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
<b>Net Income (GAAP)</b>	<b>(60,690)</b>	<b>(19,457)</b>	<b>(16,640)</b>	<b>(17,431)</b>	<b>(18,404)</b>	<b>(71,932)</b>	<b>(95,032)</b>	<b>(54,048)</b>	<b>39,303</b>	<b>122,961</b>	<b>157,568</b>	<b>191,545</b>
<b>GAAP EPS (diluted)</b>	<b>(\$3.97)</b>	<b>(\$50.45)</b>	<b>(\$2.22)</b>	<b>(\$0.59)</b>	<b>(\$0.79)</b>	<b>(\$54.05)</b>	<b>(\$3.06)</b>	<b>(\$1.52)</b>	<b>\$1.05</b>	<b>\$3.14</b>	<b>\$3.83</b>	<b>\$4.43</b>
Diluted shares outstanding	15,278	386	7,500	29,746	23,200	15,208	31,539	35,562	37,340	39,207	41,167	43,226

Source: Canaccord Genuity estimates

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Radius Health - RDUS:

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Radius Health - RDUS:

Risks to our outlook and price target include the following: the Phase 3 study for abaloparatide in osteoporosis may be negative, or fail to meet investor expectations, resulting in downside to shares and our price target. Also, Phase 3 data may be positive in terms of efficacy, but show an unexpected safety signal, also resulting in downside to our price target. Antibody formation was seen in Phase 2 studies, with one patient showing potential evidence of neutralizing antibodies. Even assuming positive Phase 3 data for subcutaneous abaloparatide in osteoporosis, FDA approval may be delayed or may not occur at all, also resulting in downside to shares and our price target. FDA may also grant approval, but require large, lengthy and expensive post-approval studies, which could also result in downside to shares and our price target. Clinical data from other osteoporosis products including anti-sclerostin antibodies from Amgen, Merck, Eli Lilly and Novartis could be viewed as superior to abaloparatide, pressuring shares. Competition from existing and new osteoporosis products could also result in lower revenues than expected, leading to downside to our estimates and the share price. Although unlikely, a paragraph 4 challenge could be filed against Lilly's Forteo, a molecule closely related to abaloparatide, which investors may interpret as increasing risk for abaloparatide, and pressuring Radius shares. Forteo was approved as an NDA, where the ANDA pathway is well established. Even though Forteo is essentially a biologic, since it is a peptide, it is feasible although unlikely that a generic challenger could emerge. FDA has approved a generic version of Lovenox, a biologic approved via the NDA pathway, although the process took many years. If a generic version of Forteo were to reach the market, usage of abaloparatide could decline, resulting in downside to our estimates and price target. Also, if FDA were to approve a generic version of Copaxone, a peptide used to treat multiple sclerosis, investors may see increased risk of a generic challenge and approval for abaloparatide, as both products are classified as NDA filings for biologic peptides. A transdermal microneedle formulation for abaloparatide may not be feasible, which investors may view as negative for life cycle management and commercial competitive positioning for Radius, pressuring shares. Even if a microneedle formulation can be developed to show equal efficacy to the subcutaneous formulation, FDA may require a full clinical study versus a bridging study, which would require additional funding and time to approval.

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	#	%	%
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Hold	338	31.35%	13.02%
Sell	45	4.17%	0%
Speculative Buy	50	4.64%	60.00%
	1078*	100.0%	

\*Total includes stocks that are Under Review

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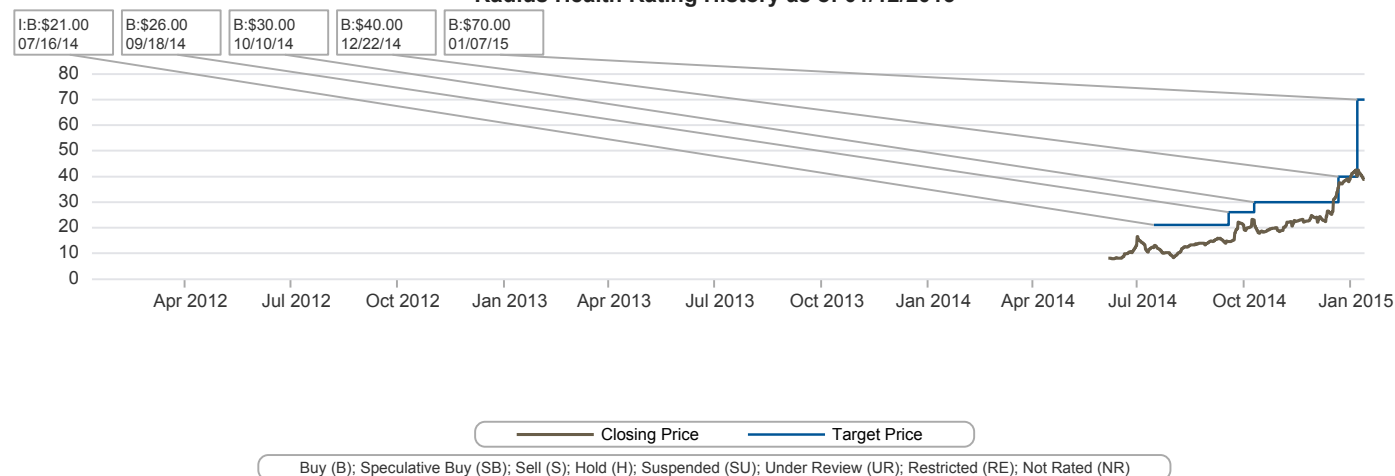
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