# **US Equity Research**

6 May 2015

BUY

Ticker

unchanged

PRICE TARGET US\$70.00

unchanged Price (6-May)

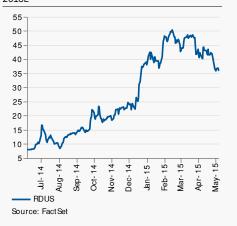
US\$36.03 RDUS-NASDAQ

52-Week Range (US\$): Avg Daily Vol (M): Shares Out. (M): Market Cap (US\$M): 7.46 - 51.22 277.6 29.7 1,072

FYE Dec	2014A	2015E	2016E
Revenue (US\$M)	0.0	0.0	82.9
Previous	0.0	0.0	82.1
EPS Adj&Dil (US\$)	(53.81)	(2.31)↑	(1.19)
Previous	(53.81)	(2.54)	(1.19)

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

Quarterly EPS Adj&Dil	Q1	Q2	Q3	Q4
2014A	(50.45)	(2.22)	(0.59)	(0.55)
2015E	(0.47)A	(0.66)	(0.58)	(0.60)
2016F	_	_	_	



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

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# **Estimates Revised**

# Abaloparatide moves forward toward NDA/MAA submission 2H15; top-line data for RAD1901 at ASCO

# Expect top-line data for ACTIVExtend 2Q15, on track for NDA, MAA submission 2H15

Radius will report top-line data on its ACTIVExtend trial, which will evaluate 6 months of alendronate post 18 months of either abaloparatide or placebo, by 2Q15, and is currently on track for NDA and MAA submission by 2H15, with a commercialization date sometime in 2016. We expect continued BMD advantage and possible fracture reduction vs. placebo, which would put the company in a favorable position going into regulatory approval as the agency has already validated this 24-month endpoint as acceptable. Additionally, recent post-hoc analysis of the ACTIVE trial demonstrated a significant 72% reduction in wrist fractures, adding to the list of positive data that has already been reported with the drug, including a high 86% vertebral fracture risk reduction, a 43% reduction in fractures at non-vertebral sites, and significant difference in time to first fracture vs. Forteo, which we believe bodes well for regulatory approval as well as drug commercialization.

### RAD1901 trial design at ASCO 2015

Radius will present the trial design for RAD1901 in a phase 1 study in metastatic breast cancer at ASCO in late May, but we **do not** expect efficacy data. The session where Radius is presenting does not allow for discussion of efficacy data, only trial design, including potential update on enrollment. It is possible that efficacy data for RAD1901 in metastatic breast cancer may surface at the San Antonio Breast Cancer Symposium in December, but we await updates from the company. Radius also plans to initiate phase 1 clinical development in the European Union for RAD1901 in metastatic breast cancer patients in 2015, which will mainly focus on pharmacodynamic properties of the compound in its engagement with estrogen receptors via FES-PET scans.

# Abaloparatide TD patch moves into the clinic in 2H15

Radius plans on starting its phase 1 trial of abaloparatide TD patch in 2H15, which we believe allows a timely rollout of the compound shortly after approval of the SQ formulation. We remind investors that although the company can only bridge patients onto the new formulation after FDA approval of the SQ injection, human PK comparability studies can be started prior to approval. Additionally, we look forward to updates on the TD patch optimization on May 11 at Transdermal Drug Delivery Conference, which can provide further PK updates for the new formulation.

## Maintain BUY, \$70 price target

We maintain our BUY rating, \$70 price target, and adjust our 2015/2016 estimated EPS based on 1Q15 earnings. We also conservatively decreased our abaloparatide sales estimate after taking a closer look at the current Forteo market, but that does not change our current price target through our EV/sales valuation methodology.

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Figure 1: RDUS income statement

Revenues	2013A	2014A	1Q15A	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
abaloparatide - US								82,902	122,229	165,478	212,938	264,914
abaloparatide - Ex-US								-	90,548	204,751	251,503	298,717
Total								82,902	212,777	370,229	464,441	563,631
Income Statement	2013A	2014A	1Q15A	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E
Total Revenue		-	-	-	-	-	-	82,902	146,677	265,806	341,204	420,247
COGS	-	-	-	-	-	-	-	16,580	29,335	53,161	68,241	84,049
Gross Profit	-	-	-	-	-	-	-	66,322	117,341	212,645	272,963	336,197
Operating Expenses												
Research and development	60,536	45,719	11,559	16,270	15,173	13,525	56,527	47,591	47,070	57,626	77,561	111,588
General and administrative	6,829	13,674	4,756	4,956	5,156	5,356	20,224	58,031	47,670	59,806	76,771	94,556
Total Operating Expense	67,365	59,393	16,315	21,226	20,329	18,881	76,751	105,622	94,740	117,432	154,332	206,143
EBITDA												
Operating income	(67,365)	(59,393)	(16,315)	(21,226)	(20,329)	(18,881)	(76,751)	(39,301)	22,602	95,212	118,631	130,054
Other income (expense), net	9,085	(2,126)	(50)	(2,126)	(50)	(2,126)	(4,352)	(2,126)	(4,352)	(2,126)	(4,352)	(2,126)
Loss on retirement of note payable												
Interest (ex pense) income, net	(2,410)	(768)	(692)	(768)	(692)	(768)	(2,920)	(768)	(2,920)	(768)	(2,920)	(768)
Accretion of preferred stock	_											
Pre-tax income (GAAP)	(60,690)	(71,501)	(17,057)	(24, 120)	(21,071)	(21,775)	(84,023)	(42,195)	15,330	92,318	111,359	127,160
Pre-tax income (non-GAAP)												
Taxes (GAAP)	_	_	-	_	_		-	<u>-</u>	5,672	34,158	41,203	47,049
Tax rate (GAAP)	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
V- 1											- ·-	- /-
Net Income (GAAP)	(60,690)	(71,501)	(17,057)	(24, 120)	(21,071)	(21,775)	(84,023)	(42,195)	9,658	58,161	70,156	80,111
GAAP EPS (diluted)	(\$3.97)	(\$53.81)	(\$0.47)	(\$0.66)	(\$0.58)	(\$0.60)	(\$2.31)	(\$1.19)	\$0.26	\$1.48	\$1.70	\$1.85
Diluted shares outstanding	15,278	17,578	36,269	36,305	36,342	36,378	31,539	35,562	37,340	39,207	41,167	43,226

Source: Company Reports, Canaccord Genuity estimates



Figure 2: RDUS Valuation

Product	Peak Sales (\$MM)	Year	NPV at launch	Estimated launch	Time to launch	Probability Adjustment	Current Value (\$MM)	Scenario probability	Value / Share (EV/Sales)
abaloparatide									
US	\$358	2022	\$561	6/1/2016	1.1	85%	\$382	100%	\$21
Ex-US - co-promote	\$346	2021	\$390	1/1/2017	1.7	85%	\$250	50%	\$11
Ex-US - roy alty	\$346	2021	\$189	1/1/2017	1.7	85%	\$133	50%	\$11
Total abaloparatide							\$632		\$44
RAD-1901									
US	\$467	2023	\$670			35%	\$235		\$10
Ex-US	\$427	2023	\$188			35%	\$66		\$9
Total RAD-1901							\$300		\$19
Total Product Value							\$632		\$64
Cash							243		\$7
Total Equity Value							875		\$70
Shares Outstanding (MM)							36		

Risk-Free Rate	2.0%
Beta	1.8
Risk Premium	6%
Discount Rate	12%
EV/Sales	5.5

Source: Company Reports, Canaccord Genuity estimates



# Appendix: Important Disclosures

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# **Target Price / Valuation Methodology:**

Radius Health - RDUS

Our \$70 price target is based on an adjusted EV/S methodologies.

# Risks to achieving Target Price / Valuation:

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 been 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 that 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.

### **Distribution of Ratings:**

# Global Stock Ratings (as of 05/06/15)

Rating	Coverag	Coverage Universe					
	#	%	%				
Buy	572	57.55%	33.22%				
Hold	337	33.90%	17.51%				
Sell	40	4.02%	2.50%				
Speculative Buy	45	4.53%	62.22%				
	994*	100.0%					

<sup>\*</sup>Total includes stocks that are Under Review

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HOLD: The stock is expected to generate risk-adjusted returns of 0-10% during the next 12 months.

**SELL**: The stock is expected to generate negative risk-adjusted returns during the next 12 months.

NOT RATED: Canaccord Genuity does not provide research coverage of the relevant issuer.



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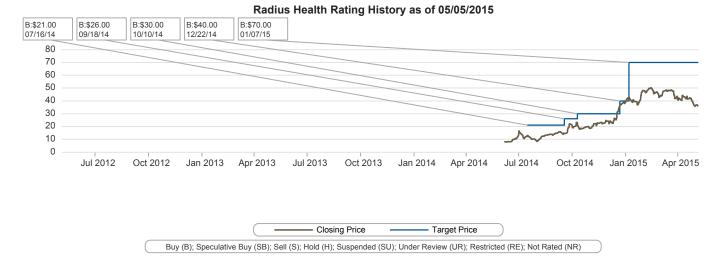
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