

Equity Research

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## Radius Health, Inc. (RDUS-\$51.73)

**Rating: BUY**

**Target Price: \$71.00**

### ACTIVEExtend Supports ACTIVE and Filing; Maintain BUY, Raising PT to \$71 from \$58

<u>EPS</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	(50.48)A	(2.22)A	(0.59)A	(0.55)A
2015E	(0.47)A	(0.45)E	(0.55)E	(0.54)E
2016E	—	—	—	—
<u>REV</u>	<u>1Q</u>	<u>2Q</u>	<u>3Q</u>	<u>4Q</u>
2014A	0.0A	0.0A	0.0A	0.0A
2015E	—	—	—	—
2016E	—	—	—	—
<u>FY</u>	<u>2014A</u>	<u>2015E</u>	<u>2016E</u>	
EPS	(4.04)A	(2.02)E	(1.01)E	
REV	0.0A	0.0E	43.9E	

- **Investment Summary:** With positive results from the abaloparatide six-month extension study, we are raising our PT to \$71 from \$58, based on a reduction in the discount rate and expansion in the multiple in our forward discounted revenue model. We believe NDA approvals are likely, and that with even a modest bite out of the Forteo market, the opportunity is meaningful. This, combined with potential upside from RAD1901, in our view, suggest to us that the valuation has room to expand.
- **Reinforcing ACTIVE.** ACTIVEExtend, the six-month extension study reinforces the 18-month results disclosed earlier this year. Specifically, previously treated abaloparatide patients did not have new vertebral fractures during the first six months on alendronate. An additional analysis of ACTIVE showed a 67% reduction in major osteoporotic fractures for the abaloparatide group versus placebo, and a 53% reduction in major osteoporotic fractures versus Forteo.
- **Increasing BMD Impressive.** Over the entire length of the study, patients treated with abaloparatide and alendronate had an average bone mineral density (BMD) increase of 12.8% at the lumbar spine, a 5.5% increase at total hip, and a 4.5% increase at the femoral neck. A substantial 20% of patients recorded a 6% increase or greater in BMD at the major sites - lumbar spine, total hip, and femoral neck.
- **Next Steps.** With these results in hand, Radius still plans to file for approval of abaloparatide-SC in 2H:15, which suggests to us that commercialization is possible sometime in late 2016. We also think that a potential partnership is a possibility, particularly with the company's patch formulation, abaloparatide-TD. We anticipate a partnership could bring greater value to the shares and reduce execution risk through the regulatory and early commercialization phase of the drug.
- **RAD1901 Could be Additive.** RAD1901 is in development for hormone positive metastatic breast cancer (mBC). A Phase I program is underway, which could be a source of upside for the shares. In addition, a Phase IIb trial with a low-dose formulation for vasomotor symptoms, is an opportunity, in our view, to further deepen the company's identity in women's healthcare, a large and growing market.
- **Valuation.** Our \$71 PT on Radius shares is based on a discounted revenue calculation for abaloparatide-SC of \$65 and \$6 for RAD1901.

#### Current Statistics

Market Cap (\$Mil)	\$1,960.1
Avg. Daily Trading Volume (3 mo.):	394,266
Shares Out (Mil):	37.890
52 Wk. Range	\$52.50-\$8.00

The Disclosure Section may be found on pages 7 - 8.

## Summary

Radius Health (Radius) is a development-stage company focused on commercializing treatments for osteoporosis and other serious endocrine-mediated disorders. However, based on the first Phase III results from its abaloparatide program (severe osteoporosis), plus a six-month extension study, Radius may have a potential replacement for Forteo, a \$1+ billion drug. Given this potential to have clinically meaningful differentiation versus Forteo (lower rate of hypercalcemia reported in the Phase III, no need for refrigeration), and a relatively short time to commercialization, we believe the valuation could expand to reflect diminished clinical risk. In addition, RAD1901, a SERD for the treatment of hormonally receptive breast cancers and vasomotor symptoms, is included in our model, which we believe can become a larger component of the valuation as the drug and the platform overall advances in development. Our \$71 price target is based on a discounted revenue calculation, based on U.S. revenues of abaloparatide-SC and the inclusion of value for RAD1901. We think there is still additional upside based on what the scope of partnership could be for abaloparatide, including abaloparatide-TD, a transdermal delivery system, that could be an important line extension.

## Abaloparatide

Abaloparatide is a synthetic peptide analog of parathyroid hormone-related protein (PTHrP) that functions as a bone anabolic treatment (grows bone). The 18-month Phase III program was conducted in 2,468 patients across 28 sites in the U.S., Europe, Asia, and Latin America. The drug's profile, we believe, is directly tied to its mechanism as a regulator of bone formation and its selectivity for receptor conformation (R<sup>0</sup>, RG), suggesting it has the ability to activate the parathyroid hormone receptor but with less downstream signaling than Forteo, a 34 N-terminal amino acid sequence of human parathyroid hormone. Forteo is able to stimulate new bone formation, but in addition to binding with high affinity to osteoblast receptors in bone, also binds to cell surface receptors in the kidney. Forteo is able to build bone but is also associated with hypercalcemia, a condition in which excess calcium remains in the bloodstream. In the top-line Phase III ACTIVE trial results, hypercalcemia rates were lower in the abaloparatide arm compared to the Forteo arm (6.0% vs. 10.8%).

**Exhibit 1. ACTIVE and ACTIVEExtend Data**

Endpoints	ACTIVE	ACTIVEExtend
New vertebral fracture reduction (primary endpoint)	-86%	-87%
	p < 0.0001	p < 0.0001
Non-vertebral fracture reduction	-43%	-52%
	p=0.0489	p=0.0168
	<b>18 months</b>	<b>25 months</b>
BMD increases at Spine	9.2%	12.8%
BMD increases at Femoral Neck	2.9%	4.5%
BMD increases at Total Hip	3.4%	5.5%

Source: Radius Health, Cantor Fitzgerald research

## Potential of Abaloparatide

We are intrigued by the potential of abaloparatide as a replacement for Forteo, as well as the opportunity to expand the market for anabolic bone agents. **In simplest terms, abaloparatide may offer unique advantages to Forteo that make it both more physician and patient-friendly.** For example, unlike Forteo, abaloparatide-SC will not need refrigeration. While Forteo also carries a warning regarding concern of osteosarcoma, this is largely seen as an observed effect in rats, and abaloparatide's carcinogenicity studies suggest the same.

## RAD1901

Licensed worldwide ex-Japan from Eisai in 2006, and just recently (3/9/15) acquiring rights in Japan, RAD1901 is a selective estrogen regulator in development for the treatment breast cancer, with a potential to impact brain metastases, and in a second formulation (lower dose) for the treatment of post-menopausal vasomotor symptoms (hot flashes). RAD1901, consistent with agents such as Evista (raloxifene), has both estrogen agonist and estrogen antagonist properties in different tissues. For instance, RAD1901 appears to protect against bone loss through its estrogen-like activities on bone, but unlike estrogen, does not stimulate endometrial growth. Preclinical studies show that RAD1901 does not stimulate replication of breast cancer cells, and has antiproliferative properties in mouse models of human breast cancer. **But RAD1901 is able to cross the blood brain barrier at pharmacological levels that are detectable in the brain, and that suggests that the drug could be a meaningful treatment to estrogen receptor positive (ER+) brain cancers that have metastasized to the brain, as well as for the treatment of vasomotor symptoms in women experiencing menopausally-related hot flashes.**

- **Vasomotor Symptoms:** A study examining RAD1901 in vasomotor symptoms was conducted in 100 healthy perimenopausal women, evaluating four doses from 10mg to 100mg of RAD1901 versus placebo. Efficacy was observed at the 10 mg dose level, with a statistically significant reduction in the frequency of moderate and severe hot flashes for the study period, as well as at weekly time intervals from two to four weeks, compared to placebo. The drug did not produce a linear dose-response, and while numerical reductions in mean severity were observed, these did not reach statistical significance. However, **given the effect on reduction in frequency of hot flashes over time and the modest safety profile of the drug, Radius believes that a larger Phase IIb study in vasomotor symptoms is warranted, and is being undertaken this year.**
- **Breast Cancer:** In breast cancer, the use of anti-estrogen agents is well established. Tamoxifen, the first SERM to be employed in the treatment of breast cancer, is used both as a therapeutic for women with metastatic disease, and as a preventative agent for ER+ early-stage breast cancer. Because RAD1901 appears to have similar anticancer properties and crosses the blood brain barrier at pharmacologic doses, **Radius is exploring this indication, enrolling a Phase Ib study – with programs both in the US and Europe.** We think there is substantial opportunity in this area, particularly given enthusiasm for Ibrance, a Pfizer drug that targets the hormonally sensitive population.

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## Valuation

We believe shares of Radius have the potential for valuation expansion to \$71. This is based on:

- **Discounted revenue** – Based on the possibility of revenues from U.S. sales of abaloparatide beginning in 2016, we are forecasting 2020 sales of approximately \$425 million. Using an 9x multiple on revenue and a 10% discount rate, Radius shares could be worth \$65 per share.
- **RAD1901** -- Now that a more clear development path of RAD1901 is established, we think the shares should incorporate at least \$200 million, or an additional \$6 per share of value for this candidate.

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## Risks

Radius Health is a development-stage company, and investment is subject to risk. These risks include but are not limited to:

- Development of new drugs carries a high failure rate, either because the drug in question fails to show efficacy, or significant safety issues arise during the clinical trial process. Additionally, regulatory authorities such as the Food & Drug Administration (FDA) and European Medicines Agency (EMA) may delay the approval process or reject Radius' clinical findings.
- The clinical landscape is crowded with hundreds of clinical trials. It is possible that other drugs will show greater benefit to patients than Radius' candidates, thus rendering potential products obsolete or non-competitive. Additionally, drug development is inherently risky, and it is possible that Radius' proprietary and partnered candidates will not be associated with successful clinical outcomes.
- Radius has rights and patents for its technologies and compounds, many of which have been licensed from third parties. There can be no assurances that such patents will not be subject to challenges, though none are known at this time.
- Radius is not cash flow positive and has not generated profits. There is no guarantee that the company will do so in the near future. The company has roughly \$200 million in cash and has stated that current development plans should allow cash to last into the end of 2016.
- The market is competitive, and we expect potential competitor drugs to abaloparatide to lose exclusivity while Radius' drugs are commercially available. There are no assurances that payors, either public or private, will adopt Radius' products over generic drugs.
- The market for Radius stock can be volatile, particularly because there is limited history as a publicly-traded company.

## Exhibit 2: Sales and Earnings by Quarter

## Radius Health, Inc.

<i>All figures in millions</i>	2015E	4Q15E	9Mos15E	3Q15E	6Mos15E	2Q15E	1Q15A	2014A	4Q14A	9Mos14A	3Q14A	6Mos14A	2Q14A	1Q14A
<b>Revenue</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>	<b>\$0.00</b>
Cost of Goods Sold	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Gross Profit	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00	\$0.00
<i>Gross Profit Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Operating Expenses														
SG&A	21.57	6.03	15.54	5.77	9.77	5.01	4.76	13.67	5.63	8.05	2.84	5.21	3.07	2.14
R&D	53.43	15.69	37.74	14.82	22.92	11.36	11.56	45.72	11.57	34.15	13.82	20.34	10.62	9.72
Total Operating Expenses	75.00	21.72	53.28	20.59	32.69	16.37	16.32	59.39	17.20	42.20	16.65	25.54	13.69	11.86
<b>Profit (Loss) from Operations</b>	<b>(\$75.00)</b>	<b>(\$21.72)</b>	<b>(\$53.28)</b>	<b>(\$20.59)</b>	<b>(\$32.69)</b>	<b>(\$16.37)</b>	<b>(\$16.32)</b>	<b>(\$59.39)</b>	<b>(\$17.20)</b>	<b>(\$42.20)</b>	<b>(\$16.65)</b>	<b>(\$25.54)</b>	<b>(\$13.69)</b>	<b>(\$11.86)</b>
<i>Operating Profit Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Interest (Expense) & Other Income (Expense)	(2.06)	(0.22)	(1.84)	(0.29)	(1.55)	(0.47)	(0.74)	(3.09)	(0.77)	(2.32)	(0.77)	(1.55)	1.08	(1.62)
Unrealized gain from marketable securities	0.06	0.00	0.06	0.00	0.06	0.00	0.06	(0.02)	(0.01)	(0.01)	(0.01)	0.00	0.00	0.00
<b>Pretax Income (Loss)</b>	<b>(\$77.00)</b>	<b>(\$21.94)</b>	<b>(\$55.06)</b>	<b>(\$20.88)</b>	<b>(\$34.18)</b>	<b>(\$16.84)</b>	<b>(\$17.00)</b>	<b>(\$62.50)</b>	<b>(\$17.97)</b>	<b>(\$44.53)</b>	<b>(\$17.43)</b>	<b>(\$27.10)</b>	<b>(\$12.61)</b>	<b>(\$13.48)</b>
<i>Pretax Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Accretion of Preferred Stock	0.00	0.00	0.00	0.00	0.00	0.00	0.00	(9.00)	0.00	(9.00)	0.00	(9.00)	(4.03)	(4.97)
<b>Net Income (Loss)</b>	<b>(\$77.00)</b>	<b>(\$21.94)</b>	<b>(\$55.06)</b>	<b>(\$20.88)</b>	<b>(\$34.18)</b>	<b>(\$16.84)</b>	<b>(\$17.00)</b>	<b>(\$71.50)</b>	<b>(\$17.97)</b>	<b>(\$53.53)</b>	<b>(\$17.43)</b>	<b>(\$36.10)</b>	<b>(\$16.64)</b>	<b>(\$8.51)</b>
<i>Net Margin</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
<i>Loss attributable to common, basic &amp; diluted</i>	<i>(\$77.00)</i>	<i>(\$21.94)</i>	<i>(\$55.06)</i>	<i>(\$20.88)</i>	<i>(\$34.18)</i>	<i>(\$16.84)</i>	<i>(\$17.00)</i>	<i>(\$76.50)</i>	<i>(\$22.97)</i>	<i>(\$58.53)</i>	<i>(\$22.43)</i>	<i>(\$36.10)</i>	<i>(\$16.64)</i>	<i>(\$19.46)</i>
<b>Basic &amp; Diluted Net Loss Per Share</b>	<b>(\$2.02)</b>	<b>(\$0.54)</b>	<b>(\$1.48)</b>	<b>(\$0.55)</b>	<b>(\$0.93)</b>	<b>(\$0.45)</b>	<b>(\$0.47)</b>	<b>(\$4.04)</b>	<b>(\$0.55)</b>	<b>(\$4.27)</b>	<b>(\$0.59)</b>	<b>(\$9.11)</b>	<b>(\$2.22)</b>	<b>(\$50.48)</b>
<i>Shares Outstanding</i>	<i>38.08</i>	<i>40.77</i>	<i>37.18</i>	<i>38.10</i>	<i>36.72</i>	<i>37.17</i>	<i>36.27</i>	<i>17.70</i>	<i>32.68</i>	<i>12.54</i>	<i>29.75</i>	<i>3.96</i>	<i>7.50</i>	<i>0.39</i>

Source: Radius Health, Cantor Fitzgerald research

**Exhibit 3: Annual Sales and Earnings**
**Radius Health, Inc.**

<i>All figures in millions, fiscal year ended June 30</i>	2020E	2019E	2018E	2017E	2016E	2015E	2014A
<b>Revenue</b>	<b>\$424.52</b>	<b>\$281.41</b>	<b>\$204.21</b>	<b>\$100.36</b>	<b>\$43.91</b>	<b>\$0.00</b>	<b>\$0.00</b>
Cost of Goods Sold	53.49	36.86	31.92	17.36	12.30	0.00	0.00
<b>Gross Profit</b>	<b>\$371.03</b>	<b>\$244.54</b>	<b>\$172.29</b>	<b>\$82.99</b>	<b>\$31.62</b>	<b>\$0.00</b>	<b>\$0.00</b>
<i>Gross Profit Margin</i>	<i>87.40%</i>	<i>86.90%</i>	<i>84.37%</i>	<i>82.70%</i>	<i>72.00%</i>	<i>NM</i>	<i>NM</i>
Operating Expenses							
G&A	45.01	40.55	36.21	31.00	26.91	21.57	13.67
R&D	72.00	64.80	58.91	52.93	45.63	53.43	45.72
Total Operating Expenses	117.01	105.36	95.12	83.93	72.54	75.00	59.39
<b>Profit (Loss) from Operations</b>	<b>\$254.02</b>	<b>\$139.19</b>	<b>\$77.17</b>	<b>(\$0.94)</b>	<b>(\$40.92)</b>	<b>(\$75.00)</b>	<b>(\$59.39)</b>
<i>Operating Profit Margin</i>	<i>60%</i>	<i>49%</i>	<i>38%</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>	<i>NM</i>
Interest Income (Expense)	(1.03)	(0.98)	(0.94)	(0.89)	(0.85)	(3.00)	(3.09)
Other Income (Expense)	1.53	1.46	1.39	1.32	1.26	0.94	(0.02)
<b>Income (Loss) from Continuing Operations</b>	<b>\$254.52</b>	<b>\$139.66</b>	<b>\$77.62</b>	<b>(\$0.51)</b>	<b>(\$40.51)</b>	<b>(\$77.06)</b>	<b>(\$62.50)</b>
Pretax Margin	59.95%	49.63%	38.01%	-0.50%	NM	NM	NM
Income Tax	0.00	0.00	0.00	0.00	0.00	0.00	0.00
Tax Rate	NM	NM	NM	NM	NM	NM	NM
Net Income	<b>\$254.52</b>	<b>\$139.66</b>	<b>\$77.62</b>	<b>(\$0.51)</b>	<b>(\$40.51)</b>	<b>(\$77.06)</b>	<b>(\$62.50)</b>
<b>Diluted Earnings (Net Loss) Per Share</b>	<b>\$4.91</b>	<b>\$2.96</b>	<b>\$1.70</b>	<b>(\$0.01)</b>	<b>(\$1.01)</b>	<b>(\$2.02)</b>	<b>(\$4.04)</b>
<b>Shares Outstanding</b>	<b>51.86</b>	<b>47.15</b>	<b>45.55</b>	<b>41.98</b>	<b>39.98</b>	<b>38.08</b>	<b>17.70</b>

Source: Radius Health, Cantor Fitzgerald research

## Company Description

*Radius Health is a development-stage biopharmaceutical firm focused on the commercialization of therapeutics for the treatment of osteoporosis and other serious endocrine-mediated disease.*

## Companies Mentioned:

Eisai Co., Ltd. (4523 - TSE): NC

Pfizer Inc. (PFE - NYSE): NC

Radius Health, Inc. (RDUS - NASDAQ): BUY

## Disclosures Appendix

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**HOLD** - denotes stocks that we suggest will provide a total return or total negative return of up to 15% over 12-month period. A HOLD rated stock is expected to perform in-line with the total average return of the analyst's industry coverage universe on a risk adjusted basis.

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### Distribution of Ratings/Investment Banking Services (IB) as of 06/18/15

Rating	Cantor		IB Serv./Past 12 Mos.	
	Count	Percent	Count	Percent
BUY [B]	96	60.76	26	27.08
HOLD [H]	56	35.44	8	14.29
SELL [S]	6	3.80	1	16.67