

## Equity Research

March 10, 2015

**Price: \$47.79** (03/9/2015) **Price Target: NA** 

### **OUTPERFORM (1)**

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### **Key Data**

Symbol NASDAQ: RDUS 52-Week Range: \$51.22 - 7.46 Market Cap (MM): \$1,762.3 Net Debt (MM): \$0.0 Cash/Share: \$31.90 Dil. Shares Out (MM): Enterprise Value (MM): \$1,718.1 ROIC NA ROE (LTM): NA BV/Share: \$0.79 Dividend: NA

FY (Dec)	2014A	2015E	2016E
Earnings Per Sh	are		
Q1	\$(50.45)	\$(0.49)	_
Prior Q1	-	\$(0.57)	-
Q2	\$(1.68)	\$(0.55)	_
Prior Q2	-	\$(0.54)	-
Q3	\$(0.59)	\$(0.63)	_
Prior Q3	-	\$(0.55)	-
Q4	\$(0.58)	\$(0.68)	_
Prior Q4	\$(0.57)	\$(0.56)	-
Year	\$(4.04)	\$(2.35)	\$(3.15)
Prior Year	\$(3.86)	\$(2.22)	-
P/E	NM	NM	NM
Consensus EPS	\$(4.04)	\$(2.33)	\$(1.95)
Consensus source: 1	homson Reuters	3	

### Revenue (MM)

Year	\$0.0	\$0.0	\$5.0
EV/S	-	-	343.6x

## Earnings Update

Radius Health

# Abaloparatide NDA And MAA Filings On-Track For H2:2015

## The Cowen Insight

Radius reported Q4 financials and provided a pipeline update. Abaloparatide, a wholly-owned candidate for osteoporosis, continues to look superior to LLY's Forteo (\$1.3B in 2014 sales) and remains on-track for NDA and MAA filings in H2. Early data on RAD1901 in ER+ breast cancer will be presented at ASCO. We continue to view RDUS shares as significantly undervalued based upon these two assets.

## Q4 Financials; Cash Through The End Of 2016

Radius reported a \$18MM net loss (vs. our \$18.6MME), ended 2014 with \$105MM in cash, and raised \$159MM in a secondary offering in January. This should fund operations to the end of 2016 and through key milestones including the first commercial sales of abaloparatide and Phase I data on RAD1901.

## **Abaloparatide Remains On Track For NDA And MAA Filings In H2:15**

Full Phase III data from abaloparatide's Phase III ACTIVE trial were presented last week at ENDO. Recall, in December, Radius announced that abaloparatide demonstrated a 86% reduction in vertebral fracture rate versus placebo (p<0.0001) and directionally superior fracture rates relative to Forteo. Furthermore, abaloparatide bested placebo and Forteo in BMD build at the hip and femoral neck at 6-, 12-, and 18-months (p<0.0001). New data presented at ENDO showed that patients who received abaloparatide experienced greater BMD gains at the wrist with a 72% reduction in wrist fracture rate versus Forteo (0.5% vs. 2.0%; p=0.0149). Furthermore, biomarker analyses utilizing CTX (a marker of bone resorption) and P1NP (a marker of bone formation) provided support from abaloparatide's lower bone resorption activity and differentiated mechanism relative to Forteo. Radius plans to commercialize the product in the U.S. via a modest sales force (~150 reps) and partner commercial rights in ex-U.S. territories. We view abaloparatide's efficacy, safety, and convenience as best-inclass, and believe it will eventually eclipse Forteo as the #1 anabolic agent.

## **Abaloparatide Patch Formulation Progressing**

Radius and partner 3M are developing a transdermal patch (abaloparatide-TD). A working prototype has achieved comparable AUC, Cmax, Tmax, and T1/2 with a desirable PK profile closely resembling that of the subcutaneous injectable in a non-human primate model. Radius expects to initiate a Phase I study in H2:15 with the goal of demonstrating PK equivalence to the abaloparatide subQ.

### Radius Now Owns Worldwide Rights To RAD1901

RAD1901 is a selective estrogen receptor degrader (SERD) for metastatic breast cancer (in Phase Ib) and vasomotor symptoms (Phase IIb trial to start in H2:15). Last week, at Cowen's Health Care conference, expert panelists expressed their excitement for the SERD class and its prospects in breast cancer. Radius expects to present early Phase Ib data from ~10 mBrCa patients at ASCO, though management cautioned that the data would likely be too immature to include much in the way of an efficacy evaluation.

Please see addendum of this report for important disclosures.

## At A Glance

## **Our Investment Thesis**

Abaloparatide is an injectable peptide analog of the PTH-related protein in Phase III development for osteoporosis. In December 2014, Radius announced positive Phase III data demonstrating a statistically significant reduction in vertebral fracture rates for abaloparatide versus placebo, and superior gains in bone mineral density and relative to Eli Lily's PTH analog, Forteo. In addition, abaloparatide achieved a statistically significant reduction in non-vertebral fractures versus placebo while the Forteo comparator arm did not. We think abaloparatide's efficacy, safety, and convenience is best-in-class, and believe it will eventually eclipse Forteo as the #1 anabolic agent. A transdermal patch formulation (abaloparatide-TD) is in development with Phase I trial to be initiated in H2:15, and could further expand the market. RDUS's other clinical candidate, RAD1901, is selective estrogen receptor degrader (SERD) with promising potential in breast cancer and other ER+ driven tumors.

## **Forthcoming Catalysts**

- Complete abaloparatide 6-month extension study in Q2:15
- Present early data from Phase Ib of RAD1901 in mBrCa at ASCO
- Submit abaloparatide NDA filing in H2

## **Base Case Assumptions**

- Subcutaneous injection of abaloparatide receives FDA approval
- Abaloparatide becomes a \$550MM+ drug in the U.S.

## **Upside Scenario**

- Radius successfully develops abaloparatide-TD, and the patch significantly expands the drug's market
- Radius successfully develops
  RAD1901 for patients with brain mets
- Radius is acquired

### **Downside Scenario**

- Abaloparatide subcutaneous injection fails to gain regulatory approval
- Abaloparatide fails to achieve \$550MM+ in sales in the U.S.

## **Price Performance**



Source: Bloomberg

## **Company Description**

Radius is developing abaloparatide, a synthetic analog of the first 34 amino acids of human parathyroid hormone related protein (hPTHrP), for osteoporosis patients with high risk for bone fractures. Abaloparatide increases patients' bone mineral density (BMD) by stimulating osteoblasts to promote new bone formation. Abaloparatide succeeded in a Phase III trial demonstrating a statistically significant reduction in vertebral fracture rates versus placebo and superior gain in BMD gains relative to Eli Lilly's Forteo (a human recombinant 34-amino acid N-terminal fragment of the parathyroid hormone), the only FDA approved anabolic agent. Radius is on-track to submit NDA filing for abaloparatide in H2:15 while an abaloparatide patch formulation is progressing. Radius's second drug candidate RAD1901 functions as a selective estrogen receptor down-regulator (SERD) at a high dose for mBrCa and a modulator (SERM) at a low dose for vasomotor symptoms.

### **Analyst Top Picks**

	Ticker	Price (03/9/2015)	Price Target	Rating
Alexion Pharmaceuticals	ALXN	\$184.91	\$206.00	Outperform
Biogen Idec	BIIB	\$415.51	\$425.00	Outperform
Celgene	CELG	\$118.41	\$146.00	Outperform

### **Investment Thesis**

Radius's lead candidate, abaloparatide, is an injectable peptide analog of the PTHrelated protein in Phase III development for osteoporosis. In December 2014, Radius announced positive Phase III data demonstrating a statistically significant reduction in vertebral fracture rates for abaloparatide versus placebo, and superior gains in bone mineral density and relative to Eli Lily's PTH analog, Forteo. In addition, abaloparatide achieved a statistically significant reduction in non-vertebral fractures versus placebo while the Forteo comparator arm did not. Radius anticipates NDA and MAA filings for abaloparatide in H2:15 and intends to market abaloparatide on its own in the U.S. Forteo sales were over \$1.3B worldwide in 2014, and we think abaloparatide could expand this market by virtue of its superior potency, convenience, and safety. Abaloparatide is also being developed as a patch for transdermal delivery (abaloparatide-TD). Radius's second candidate, RAD1901, is a selective estrogen receptor degrader or SERD for estrogen receptor-positive breast cancer. SERDs are a relatively new and exciting class of therapeutics that has the ability to treat hormoneresistant tumors. Radius initiated a Phase Ib trial on RAD1901 in ER+ HER2-breast cancer patients with brain metastases in January 2015 following the announcement of Phase I data in healthy volunteers that supports QD dosing and demonstrated favorable safety and tolerability. Radius also plans to develop RAD1901 as selective estrogen receptor modulator (SERM) for vasomotor symptoms and anticipates the initiation of a Phase IIb study in H2:2015. We expect RDUS share to outperform as abaloparatide advances to the market and RAD1901 achieve proof-of-concept.

## Radius Health - Upcoming Milestones/Events

Indication/Milestone	Timing
24-month fracture data from abaloratide's Phase III extension trial (ACTIVE-Extend)	Q2:15
Early Phase I data on RAD1901 in ER+ breast cancer at ASCO	June
NDA and MAA submissions for abaloparatide	H2:15
Initiate Phase IIb study on RAD1901 for vasomotor symptoms	H2:15
Initiate clinical evaluation of optimized abaloparatide-TD patch	H2:15
Initiation of Phase I trials of RAD1901 in breast cancer patients with brain mets in Europe	2015
Publication of Phase III ACTIVE trial data	2015
Sign ex-U.S. commercial marketing partner for abaloparatide	2015-16
Potential FDA and EMA approvals for abaloparatide	H2:16
U.S. commercial launch of abaloparatide	Late 2016

Source: Cowen and Company

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## Radius Health Quarterly P&L Model (\$MM)

	Q1:14A	Q2:14A	Q3:14A	Q4:14A	2014A	Q1:15E	Q2:15E	Q3:15E	Q4:15E	2015E
Abaloparatide-SC U.S. Sales Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Abaloparatide-SC ex-U.S. Royalty Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total Revenue	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
COGS	-	-	-	-	_	-	-	-	-	-
GMs										
R&D	9.7	10.6	13.8	11.6	45.7	13.0	14.0	16.0	17.0	60.0
SG&A	2.1	3.1	2.8	5.6	13.7	5.0	6.5	7.5	8.5	27.5
Other	-	-	-	-	_	-	-	-	-	-
Total Operating Expenses	11.9	13.7	16.7	17.2	59.4	18.0	20.5	23.5	25.5	87.5
Income from Operations	(11.9)	(13.7)	(16.7)	(17.2)	(59.4)	(18.0)	(20.5)	(23.5)	(25.5)	(87.5)
Op Margins										
Interest and Investment Income	0.0	0.0	0.0	0.1	0.1	0.1	0.1	0.1	0.1	0.4
Other Income (expense)	(2.2)	1.5	0.0	(0.0)	(0.7)	0.0	0.0	0.0	0.0	0.0
Interest expense	(0.4)	(0.5)	(0.8)	(0.8)	(2.5)	(0.5)	(0.5)	(0.5)	(0.5)	(2.0)
Net Loss	(14.5)	(12.6)	(17.4)	(18.0)	(62.5)	(18.4)	(20.9)	(23.9)	(25.9)	(89.1)
Acretion of Preferred Stock	(5.0)	0.0	0.0	0.0	(5.0)	0.0	0.0	0.0	0.0	0.0
Unrealized Loss from Marketable Securities		0.0	(0.0)	(0.0)	(0.0)					
Pre Tax Earnings (Losses)	(19.5)	(12.6)	(17.4)	(18.0)	(62.5)	(18.4)	(20.9)	(23.9)	(25.9)	(89.1)
Tax rate	0%	0%	0%	0%	0%	0%	0%	0%	0.0	0%
Income Tax	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	(\$19.5)	(\$12.6)	(\$17.4)	(\$18.0)	(\$71.5)	(\$18.4)	(\$20.9)	(\$23.9)	(25.9)	(89.1)
GAAP EPS	(\$50.45)	(\$1.68)	(\$0.59)	(\$0.55)	(\$4.04)	(\$0.49)	(\$0.55)	(\$0.63)	(\$0.68)	(\$2.35)
Diluted Shares	0.4	7.5	29.7	32.7	17.7	37.5	37.7	38.0	38.2	37.9

Source: Cowen and Company

## Radius Health Annual P&L Model (\$MM)

	2014A	2015E	2016E	2017E	2018E	2019E
Abaloparatide-SC U.S. Sales Revenue	0.0	0.0	5.0	70.0	125.0	175.0
Abaloparatide-SC ex-U.S. Royalty Revenue	0.0	0.0	0.0	0.8	6.0	15.0
Total Revenue	0.0	0.0	5.0	70.8	131.0	190.0
COGS		-	0.9	10.5	17.5	23.3
GMs	0%	0%	83%	85%	86%	87%
R&D	45.7	60.0	70.0	80.0	85.0	90.0
SG&A	13.7	27.5	65.0	80.0	90.0	95.0
Total Operating Expenses	59.4	87.5	135.9	170.5	193.4	208.3
Income from Operations	(59.4)	(87.5)	(130.9)	(99.8)	(62.4)	(18.3)
Op Margins	0%	0%	0%	0%	0%	NA
Interest and Investment Income	0.1	0.4	0.5	0.5	0.5	0.5
Other Income (expense)	(0.7)	0.0	0.0	0.0	0.0	0.0
Interest expense	(2.5)	(2.0)	(2.0)	(2.0)	(2.0)	(2.0)
Net Loss	(62.5)	(89.1)	(132.4)	(101.3)	(63.9)	(19.8)
Acretion of Preferred Stock	(5.0)	0.0	0.0	0.0	0.0	0.0
Pre Tax Earnings (Losses)	(62.5)	(89.1)	(132.4)	(101.3)	(63.9)	(19.8)
Tax rate	0%	0%	0%	0%	0%	0%
Income Tax	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Loss)	(\$71.5)	(\$89.1)	(\$132.4)	(\$101.3)	(\$63.9)	(\$19.8)
GAAP EPS	(\$4.04)	(\$2.35)	(\$3.15)	(\$2.35)	(\$1.30)	(\$0.40)
Diluted Shares	17.7	37.9	42.0	43.0	49.0	50.0

Source: Cowen and Company

# Valuation Methodology And Risks

## Valuation Methodology

## **Biotechnology:**

In calculating our 12-month target price, we employ one or more valuation methodologies, which include a discounted earnings analysis, discounted cash flow analysis, net present value analysis and/or a comparable company analysis. These analyses may or may not require the use of objective measures such as price-to-earnings or price-to-sales multiples as well as subjective measures such as discount rates.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe there are any good methodologies for assigning a specific target price to such stocks.

### **Investment Risks**

## **Biotechnology:**

There are multiple risks that are inherent with an investment in the biotechnology sector. Beyond systemic risk, there is also clinical, regulatory, and commercial risk. Additionally, biotechnology companies require significant amounts of capital in order to develop their clinical programs. The capital-raising environment is always changing and there is risk that necessary capital to complete development may not be readily available.

## **Risks To The Price Target**

Radius Health is unprofitable, has no approved products, and will likely need to raise additional capital from the public markets prior to turning profitable. There is no guarantee that abaloparatide's Phase III study will meet its primary endpoint of fracture reduction. Even if successful, abaloparatide may face other commercial and competitive risks that thwart adoption.

We make investment recommendations on early stage (pre-commercial) biotechnology companies based upon an assessment of their technology, the probability of pipeline success, and the potential market opportunity in the event of success. However, because these companies lack traditional financial metrics, we do not believe it there are any good methodologies for assigning a specific target price to such stocks.

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## Addendum

## **Stocks Mentioned In Important Disclosures**

Ticker	Company Name
ALXN	Alexion Pharmaceuticals
BIIB	Biogen Idec
CELG	Celgene
RDUS	Radius Health

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Outperform (1): The stock is expected to achieve a total positive return of at least 15% over the next 12 months

Market Perform (2): The stock is expected to have a total return that falls between the parameters of an Outperform and Underperform over the next 12 months

Underperform (3): Stock is expected to achieve a total negative return of at least 10% over the next 12 months

Assumption: The expected total return calculation includes anticipated dividend yield

Cowen and Company Rating System until May 25, 2013

Outperform (1): Stock expected to outperform the S&P 500

Neutral (2): Stock expected to perform in line with the S&P 500

Underperform (3): Stock expected to underperform the S&P 500

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Assumptions: Time horizon is 12 months; S&P 500 is flat over forecast period

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Buy – The fundamentals/valuations of the subject company are improving and the investment return is expected to be 5 to 15 percentage points higher than the general market return

Sell – The fundamentals/valuations of the subject company are deteriorating and the investment return is expected to be 5 to 15 percentage points lower than the general market return

Hold – The fundamentals/valuations of the subject company are neither improving nor deteriorating and the investment return is expected to be in line with the general market return

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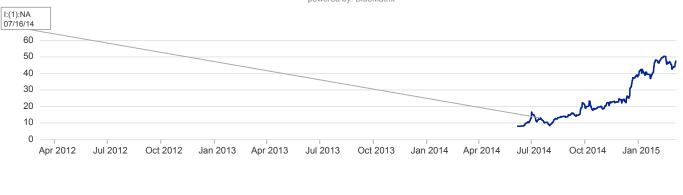
Rating	Count	Ratings Distribution	Count	IB Services/Past 12 Months
Buy (a)	461	60.50%	109	23.64%
Hold (b)	288	37.80%	14	4.86%
Sell (c)	13	1.71%	0	0.00%

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### Radius Health Rating History as of 03/06/2015

powered by: BlueMatrix



Closing Price Target Price

## Alexion Pharmaceuticals Rating History as of 03/07/2015

powered by: BlueMatrix



Closing Price Target Price

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## Celgene Rating History as of 03/07/2015







### **Legend for Price Chart:**

I = Initiation | 1 = Outperform | 2 = Market Perform | 3 = Underperform | UR = Price Target Under Review | T = Terminated Coverage | \$xx = Price Target | NA = Not Available | S=Suspended

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### Radius Health

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