

Today's Changes \$26.00 from \$21.00

# **Radius Health**

RDUS: NASDAQ: US\$14.59

BUY

**Target: US\$26.00 ↑** 

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#### **COMPANY STATISTICS:**

Forecast Return:	78.2%
Shares Out (M):	7.50
Market Cap (M):	US\$109.4
52-week Range:	7.46 - 17.32
Avg. Daily Vol. (000s):	53.0

#### **EARNINGS SUMMARY:**

FYE Dec		2013A	2014E	2015E	2016E
Revenue (M):		0.0	0.0	0.0	82.1
EPS:		(3.97)	(54.39)	(2.78)	(1.53)
Revenue (M):	Q1				
	Q2				
	Q3				
	Q4				
Total		0.0	0.0	0.0	82.1
EPS:	Q1		(50.45)		
	Q2		(2.22)		
	Q3		(0.88)		
	Q4		(0.84)		
Total		(3.97)	(54.39)	(2.78)	(1.53)

#### **SHARE PRICE PERFORMANCE:**



Source: Interactive Data Corporation

#### **COMPANY DESCRIPTION:**

Radius is a biotechnology company focused on discovering, developing, and commercializing drugs for endocrine disorders. Its wholly owned lead asset is abaloparatide, in Phase 3 for treatment of postmenopausal osteoporosis.

All amounts in US\$ unless otherwise noted.

Life Sciences -- Biotechnology

# HUGE MARKET FOR ABALOPARATIDE; EXPECT POSITIVE PHASE 3 DATA YE14, RAD1901 POTENTIAL

# **Investment highlights**

# \$2.5B injectable osteoporosis market, estimate \$649M peak sales

We view the ~\$2.5B market for abaloparatide and \$649M peak sales estimate as highly attractive, given RDUS shares are pricing in only a ~40% chance of approval at present. We believe abaloparatide will have better efficacy and safety versus Forteo, taking market share on approval.

## Expect positive Phase 3 data YE14, strong risk/reward vs Forteo

We expect Phase 3 data for abaloparatide vs. Forteo during December 2014, which should drive shares substantially higher. The study has been derisked based on a similar mechanism of action to Forteo, but superior spine, femoral neck and total hip BMD vs. Forteo. Though not powered for hip fracture due to small sample size, we believe physicians will focus on the secondary endpoint of non-vertebral fractures, including hip fractures.

## Competition manageable after ASBMR meeting

Merck presented Phase 3 data for oral odanacatib this weekend at the ASBMR meeting which showed reduction in fracture risk due to large sample size, but was clouded by toxicity profiles including increased stroke risk, a positive for RDUS. Deep dive analysis shows better BMD increase for abaloparatide at spine, hip, and femoral neck when compared to Merck's compound and similar uptake vs. Amgen's romosozumab.

### Raising price target to \$26, expect positive Phase 3 data

We are raising our price target to \$26 based on higher confidence in positive Phase 3 data for abaloparatide. We view the Phase 3 trial as substantially de-risked based on prior head-to-head Phase 2 data versus Forteo. Also, we believe that the very strong five-year monkey data presented at ASBMR this past weekend adds additional evidence of strong efficacy for abaloparatide.

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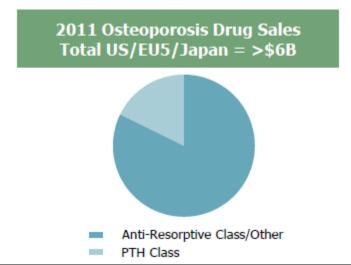
The recommendations and opinions expressed in this research report accurately reflect the Investment Analyst's personal, independent and objective views about any and all the Designated Investments and Relevant Issuers discussed herein. For important information, please see the Important Disclosures section in the appendix of this document.



# LARGE \$2.5B INJECTABLE OSTEOPOROSIS MARKET, ESTIMATE \$649M PEAK SALES

The injectable osteoporosis market is ~\$2.5B at present, but represents only a small portion of the overall osteoporosis market. Improved injectable therapies such as abaloparatide could expand this market going forward. Currently, the injectable market consists of only Prolia and Forteo sales, with 2013 revenues of \$1.4B and \$1.2B, respectively. The figure below demonstrates that Forteo makes up <20% of the total osteoporosis drug sales, suggesting upside for abaloparatide assuming improved efficacy and safety. Importantly, injectable osteoporosis drugs have historically expanded the market when introduced, which bodes well for abaloparatide, in our view.

Figure 1: Total Osteoporosis Drug Sales



Source: Radius Health Company Presentation



# **FAVORABLE RISK/REWARD COMPARED TO FORTEO**

The mechanism of action of abaloparatide appears to have more selective binding on parathyroid hormone 1 (PTH1) than Forteo, which has shown better efficacy and safety head-to-head in Phase 2, suggesting reduced development risk, in our view. Unlike Forteo which only binds to one conformation state of PTH1, abaloparatide binds to both of PTH1's conformational states. In addition, abaloparatide has PTH1 engagement similar to the 34-amino acid peptide of Parathyroid hormone-related peptide (hPTHrP), inducing the PTH1 receptor to be in a more active state vs. Forteo.

PTH1R has two conformational states with different signaling

L R<sup>0</sup> L R\*G

Kd<sub>High</sub>

PTH(1-34)

Prolonged

cAMP signaling

PTH1R has two conformational states with different signaling

Figure 2: Two conformational states of PTH1

Source: Radius Health Company Presentation

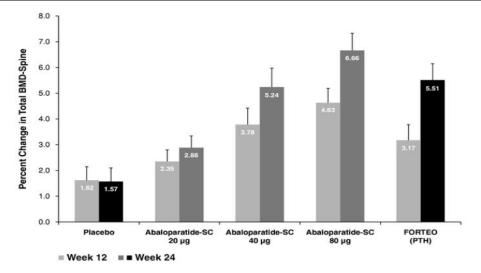
The improved efficacy of the drug was seen in a randomized, placebo-controlled Phase 2 study, the trial evaluated postmenopausal women with severe osteoporosis with 221 patients randomized to receive abaloparatide, Forteo, or placebo.



The mean percent change in lumbar spine BMD at 24 weeks was +1.6% with placebo, +6.7% with abaloparatide 80 ug, and +5.5% with Forteo (Figure 3).

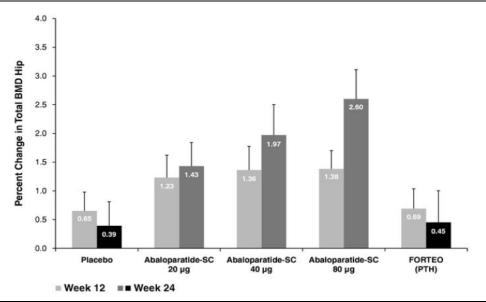
A marked increase in total hip BMD was also seen, where the change was 0.4% with placebo, +2.6% with abaloparatide 80 ug, and +0.5% with Forteo (Figure 4).

Figure 3: Percent Change from Baseline at weeks 12 and 24 in Total Spine BMD



Source: Radius Health Company Presentation

Figure 4: Percent Change from Baseline at weeks 12 and 24 in Total Hip BMD



Source: Radius Health Company Presentation



55 of the 69 eligible patients received an additional 24 weeks of treatment to see if the effect of BMD continued to improve. Lumbar spine BMD continued to increase, with a change at 48 weeks of +0.7% with placebo, +12.9% with abaloparatide 80  $\mu$ g, and +8.6% with Forteo (Figure 5). Similarly, gains in hip BMD were also seen, with a mean change for the total hip +0.7% with placebo, +2.7% with abaloparatide 80  $\mu$ g, and +1.3% with Forteo, and at the femoral neck +1.0% with placebo, +4.1% with BA058 80  $\mu$ g, and +2.2% with Forteo.

16.0 14.0 Percent Change in Total BMD Spine 12.0 10.0 8.0 6.0 4.0 2.0 0.0 FORTEO 20 µg Abaloparatide-SC Abaloparatide-SC Abaloparatide-SC 40 µg 80 ug (PTH) ■ Week 12 (Month 3) ■ Week 24 (Month 6) Week 48 (Month 12)

Figure 5: Percent Change from Baseline at weeks 12 and 24 and 48 in Total Spine BMD

Source: Radius Health Company Presentation.

Patients taking abaloparatide generally tolerated the drug well with adverse events reported in 66 (30%) of 221 patients during the initial 24 weeks of treatment and 16 (29%) of 55 patients during the extension. Importantly, there was about 50% reduction in occurrence of hypercalcemia compared to Forteo. This not only reflects better safety, but also demonstrates the superior mechanism of action of abaloparatide, indicating a less resorptive, catabolic effect that currently plagues Forteo while having notable anabolic efficacy. These better efficacy and tolerability data seen in the Phase 2 study gave rise to the launch of their Phase 3 study of abaloparatide 80 ug vs. placebo vs. Forteo with primary endpoint of reduction in new vertebral fractures between the groups. We expect positive results in the head-to-head Phase 3 trial vs. Forteo by December 2014, driving market value for Radius.

Although preclinical, RDUS presented very interesting results with their monkey trial. Treatment with abaloparatide showed marked positive gains in bone mass after 16 months of abaloparatide treated at the lumbar spine and femoral neck. Remarkably, there was a positive correlation in the vertebral cores in strength parameters through mechanical testing. Correlation analysis showed increased



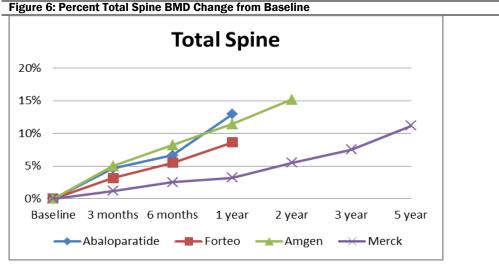
values in strength data as pharmacological doses increased. Overall correlation analysis not only showed positive effects of abaloparatide in bone mass gains, but bone quality as well. It should be noted that Forteo previously had monkey data as well which showed increased BMD, but no mechanical strength. Though preclinical model, this data helps establish a positive correlation of increased BMD with improvement in clinical outcomes, which will remain important for physicians in their decision for treatment options.

## **COMPETITION IN ADVANCED OSTEOPOROSIS MANAGEABLE**

Despite the competition Amgen, Lilly, Novartis and Merck via anti-sclerostin antibodies and cathepsin-K inhibitors, we expect superior efficacy for abaloparatide to represent the benchmark for future therapies. We feel the main competitor is Merck's oral cathepsin-K inhibitor, with potential FDA approval during 2H14.

Deep dive analysis in terms of BMD increase from baseline is reported below. Please note that these are not head-to-head trials and our data are based on updated presentations from ASBMR data, with abaloparatide up to 48 weeks of data, Amgen's romosozumab 2 year data, and Merck's odanacatib 5 year update.

In terms of total spine BMD increase from baseline, we can see that Amgen's romosozumab seems to have a faster BMD increase in 6 months (+6.7% vs. +8.2%), but this levels off after a year (Figure 6). Merck's odanacatib has the slowest uptake with 5 year BMD change of +11.2%, while abaloparatide was +12.94% at only 1 year. We believe physicians will use abaloparatide in more severe patients based on the fact of faster increase in BMD.



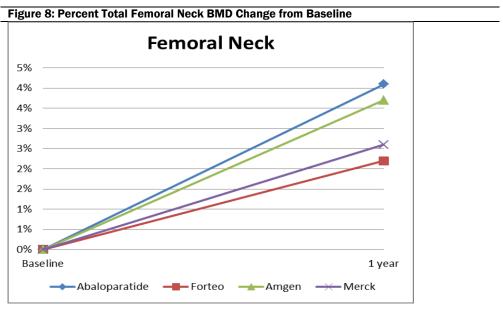
Source: ASBMR Abstract data, Canaccord Genuity, Inc.



Similar findings were seen with BMD change from baseline in total hip and femoral neck. Figure 7shows similar velocity of BMD uptake compared to Amgen's drug, with Merck's cat-K inhibitor and Forteo lagging behind. Merck's 5 year data shows total hip BMD increase of +9.5%, a target we believe abaloparatide can surpass given the slope of the curve. In Figure 8, we see faster 1 year increase of abaloparatide (+4.1%) compared to Forteo (+2.2%), Amgen (3.7%), and Merck (+2.6%) in femoral neck.

Figure 7: Percent Total Hip BMD Change from Baseline **Total Hip** 10% 8% 6% 4% 2% 0% 3 months 6 months 1 year 2 year 3 year 5 year Abaloparatide Forteo -Amgen → Merck

Source: ASBMR Abstract data, Canaccord Genuity, Inc.



Source: ASBMR Abstract data, Canaccord Genuity, Inc.



Abaloparatide is targeted for NDA submission in 1H15 to be a best-in-class anabolic agent. We expect launch by 1H16, which we believe will establish the drug as standard of care in advanced osteoporosis before newer competitors become available.

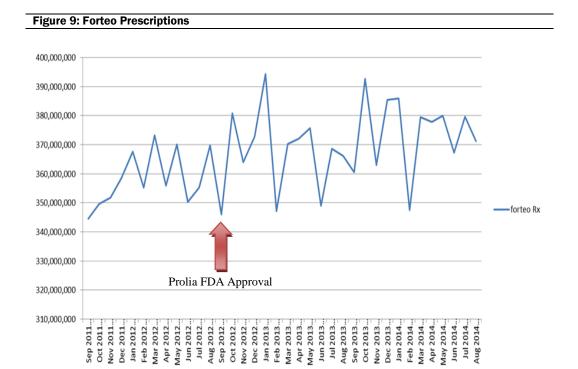
# MERCK'S ODANACATIB STROKE RISK SEEN AT ASBMR, POSITIVE FOR RADIUS

It should be noted the ASBMR presentation from Merck's odanacatib did show statistical significant relative risk reductions in hip fractures, non-vertebral fractures, and vertebral fractures, a strong clinical marker to guide physician decisions in osteoporosis. However, safety data showed an increased risk of stroke in the odanacatib group (1.4%) vs. placebo group (1.1%). Though this was not statistically significant, the hazard ratio was 1.28, with a 95% confidence interval pushing the margin of limit of CI 0.97 – 1.70. We feel this safety concern may raise concern to physicians about long-term use with this drug, potentiating further market uptake of abaloparatide. Even though non-vertebral fractures remain a secondary endpoint due to the limited patient population of the Phase 3 study, we believe a positive endpoint and fast BMD uptake in total spine, hip, and femoral neck will position this drug as first line therapy for physicians.



# FORTEO SALES CONSISTENT DESPITE COMPETITION, POSITIVE FOR ABALOPARATIDE

We ran IMS data for Forteo over the years and did not find an effect on Forteo prescriptions after the introduction of Amgen's Prolia for men with osteoporosis in September 2012, giving us confidence that further competition will have small effect once abaloparatide comes to the market. We believe abaloparatide will take significant market share from Forteo's \$1.1B market share due to increased efficacy and safety without hindrance from newer agents like odanacatib and romosozumab.



Source: Canaccord Genuity, IMS database



# RAD1901 FOR METASTATIC BREAST CANCER UNIQUE, POTENTIAL VALUE DRIVER

RAD1901 is the only oral estrogen receptor blocker for breast cancer that crosses the blood brain barrier, which represents substantial upside if successful. At higher doses, RAD1901 acts like a selective estrogen down-regulator (SERD) with the ability to induce estrogen receptor downregulation. Compared to aromatase inhibitors and selective estrogen receptor modulators, SERDs should prevent ER-dependent, ligand-independent resistance commonly seen with these therapies and work on AI/SERM resistant tumors. We believe there is potential to dominate a niche area of high unmet need, currently controlled by Faslodex with \$654M in worldwide revenues.

ΑI (aromatase inhibitor) Blocks generation androgen of estrogen estrogen **ER** RAD1901 - Low Dose RAD1901 - High Dos **SERM SERD ER** Competitively Induces ER inhibits ER degradation **ER** Activates ER

Figure 10: Mechanism of Action for RAD1901

Source: Canaccord Genuity, Inc.

Interestingly, at lower doses, RAD1901 is a selective estrogen receptor modulator (SERM) that competitively inhibits estrogen receptors. Due to this unique dual mechanism of this drug, Radius is also conducting a Phase 2 proof-of-concept study of RAD1901 at lower doses to demonstrate reduction in frequency and severity of hot flashes. The Phase 2 trial could serve as a further catalyst in driving RDUS price performance.



Figure 11: Radius Income Statement

		Radius Health, Inc.										
(000's) [FY - DEC]	20424	10114	20444	20145	4Q14E	20445	2015E	2016E	2017E	2018E	2019E	2020E
Revenues abaloparatide - US	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2013E	82,120	239,867	357,419	465,944	583,042
abaloparatide - Ex-US								-	90,548	204,751	251,503	298,717
Total								82,120	330,415	562,170	717,447	881,759
iotai								02,120	330,413	362,170	717,447	001,759
Income Statement	2013A	1Q14A	2Q14A	3Q14E	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
Total Revenue	_	_	_	_	-	_	_	82,120	264,315	457,747	594,210	738,375
COGS	_	_	_	_			_	16,424	52,863	91,549	118,842	147,675
Gross Profit	_	_	_	_	_	=	_	65,696	211,452	366,198	475,368	590,700
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Operating Expenses												
Research and development	60,536	9,717	10,618	14,142	18,096	52,573	78,094	63,671	60,593	70,860	90,593	124,479
abaloparatide-SC	45,977	8,107	9,728	11,674	14,009	43,518	31,170	21,819	15,273	15,273	15,273	15,273
abaloparatide-TD	11,459	185	278	416	624	1,503	24,975	17,483	12,238	8,566	5,996	4,198
RAD1901	-	-			1,000	1,000	12,100	14,520	23,232	37,171	59,474	95,158
RAD140	-	-				-	-					
other	3,100	1,425	1,710	2,052	2,462	7,649	9,850	9,850	9,850	9,850	9,850	9,850
General and administrative	6,829	2,139	3,070	2,500	2,700	10,409	13,200	57,484	85,902	102,993	133,697	166,134
Total Operating Expense	67,365	11,856	13,688	16,642	20,796	62,982	91,294	121,155	146,495	173,854	224,291	290,613
EBITDA												
Operating income	(67,365)	(11,856)	(13,688)	(16,642)	(20,796)	(62,982)	(91,294)	(55,459)	64,957	192,344	251,078	300,087
Other income (expense), net	9,085	(2,233)	1,727	1,727	1,727	2,948	9,350	2,948	9,350	2,948	9,350	2,948
Loss on retirement of note payable	3,000	(2,200)	(203)	1,121	1,727	2,540	3,000	2,540	3,000	2,540	3,000	2,540
Interest (ex pense) income, net	(2,410)	(399)	(445)	(445)	(445)	(1,734)	(4,358)	(1,734)	(4,358)	(1,734)	(4,358)	(1,734)
Accretion of preferred stock	(2, 0)	(4,969)	(4,031)	()	(1.3)	(.,/	(1,000)	(.,,	(1,000)	(.,,	(1,000)	(1,104)
Pre-tax income (GAAP)	(60,690)	(19,457)	(16,640)	(15,360)	(19,514)	(70,971)	(86,302)	(54,245)	69,949	193,558	256,070	301,301
Pre-tax income (non-GAAP)				,			. ,	. ,				
Tax es (GAAP)	_	_	_	_	<u>-</u>		_	_	25,881	71,617	94,746	111,481
Tax rate (GAAP)	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%	37%
,-									· · ·			
Net Income (GAAP)	(60,690)	(19,457)	(16,640)	(15,360)	(19,514)	(70,971)	(86,302)	(54,245)	44,068	121,942	161,324	189,820
GAAP EPS (diluted)	(\$3.97)	(\$50.45)	(\$2.22)	(\$0.88)	(\$0.84)	(\$54.39)	(\$2.78)	(\$1.53)	\$1.18	\$3.11	\$3.92	\$4.39
Basic shares outstanding	15,278	386	7,500	17,400	23,200	12,121	31,539	35,562	37,340	39,207	41,167	43,226
Diluted shares outstanding	15,278	386	7,500	17,400	23,200	12,121	31,539	35,562	37,340	39,207	41,167	43,226

Source: Canaccord Genuity estimates, Company reports

Please note that diluted EPS changed from our previous estimate due to accretion of preferred stock which we now included in our net loss. This does not reflect a decrease of our EPS valuation since this was simply an accounting change.

18 September 2014

Figure 12: Radius Valuation projection

Product	Peak Sales (\$MM)	Year	NPV at launch	Probability Adjustment	Current Value (\$MM)	Scenario probability	Value / Share
abaloparatide							
US	\$649	2022	\$1,073	65%	\$521	100%	\$18
Ex-US - co-promote	\$346	2021	\$390	65%	\$164	50%	\$3
Ex-US - roy alty	\$346	2021	\$189	65%	\$123	50%	\$2
Total abaloparatide					\$685		\$23
Total Product Value					685		\$24
Cash					60		\$2
Total Equity Value					745		\$26
Shares Outstanding (MM)					29		

Risk-Free Rate	3.0%
Beta	1.8
Risk Premium	6%
Discount Rate	14%

Source: Canaccord Genuity estimates, Company reports



#### **Investment risks**

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.



### **APPENDIX: IMPORTANT DISCLOSURES**

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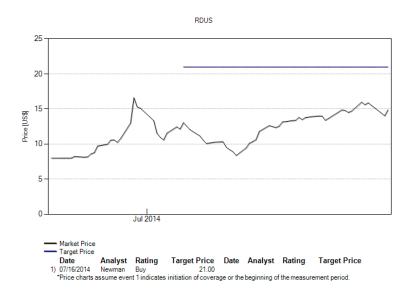
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**Site Visit:** 

An analyst has visited Radius Health's material operations in Cambridge, Massachusetts. No payment or reimbursement was received from the issuer for the related travel costs.

#### Price Chart:\*



# **Distribution of Ratings:** Global Stock Ratings (as of 3 July 2014)

Coverage Universe						
Rating	#	IB Clients %				
Buy	602	61.2%	38.2%			
Speculative Buy	49	5.0%	55.1%			
Hold	290	29.5%	13.1%			
Sell	41	4.2%	7.3%			
	984	100.0%				

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

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**BUY:** The stock is expected to generate risk-adjusted returns of over 10% during the next 12 months. **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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**SPECULATIVE:** Stocks bear significantly higher risk that typically cannot be valued by normal fundamental criteria. Investments in the stock may result in material loss.

#### Canaccord Genuity Research Disclosures as of 18 September 2014

•	
Company	Disclosure
Radius Health	1A, 2, 3, 5, 7

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  - B. non-investment banking securities-related services.
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