

## **Radius Health**

RDUS: NASDAQ: US\$22.07

**BUY** 

**Target: US\$30.00** 

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## **COMPANY STATISTICS:**

Forecast Return:	35.9%
Shares Out (M):	29.7
Market Cap (M):	US\$656.5
52-week Range:	7.46 - 27.70
Avg. Daily Vol. (000s):	150.1

#### **EARNINGS SUMMARY:**

FYE Dec		2013A	2014E	2015E	2016E
Revenue (N	1):	0.0	0.0	0.0	82.1
EPS:		(3.97)	(54.05)	(3.06)	(1.52)
Revenue					
(M):	Q1	0.0	0.0	0.0A	-
	Q2	0.0	0.0	0.0A	-
	Q3	0.0	0.0	0.0	-
	Q4	0.0	0.0	0.0	-
Total		0.0	0.0	0.0	82.1
EPS:	Q1		(50.45)	(0.68)A	-
	Q2		(2.22)	A(88.0)	-
	Q3	0.00	(0.59)	(0.75)	-
	Q4	0.00	(0.79)	(0.75)	-
Total		(3.97)	(54.05)	(3.06)	(1.52)

### **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

## SABCS PREVIEW ON RADIUS: EXPECT **TOP-LINE DATA FOR RAD1901 IN BCBM -- DECEMBER 11**

## **Investment highlights**

## Expect RAD1901 MTD data in healthy volunteers

Radius will be presenting top-line Phase 1 data for RAD1901, a selective estrogen receptor degrader (SERD), in healthy volunteers on December 11, focusing on pharmacodynamics endpoint by using 18F-FES PET scans to illuminate uptake of RAD1901 into estrogen receptors (ER). We believe the results will be positive, since recent data presented in September demonstrated rapid suppression of ER receptors (as fast as 6 days post dose) in the uterus and pituitary in 40 patients without achieving maximum tolerated dose, demonstrating room to increase therapeutic efficacy.

## Positive data catalyst for Phase 1B trial, CNS penetration key

We believe RAD1901's potential to cross the blood brain barrier could be advantageous vs. current therapies, with potential to penetrate a ~\$540M market in breast cancer brain metastasis (BCBM). The company will measure levels of RAD1901 in the CSF to confirm brain penetration, which we believe will be critical in demonstrating proof of concept in BCBM patients as the company moves forward into Phase 1B trials. We remind investors that no therapies to date target BCBM, giving RAD1901 potential to capture significant market share if results remain positive. Although we do not model RAD1901 into our valuation, we believe the drug can address ~\$1.4B market total in metastatic breast cancer.

## Spotlight also on ARN-810 (Roche's SERD), manageable

We also anticipate top-line data for the company's main competitor, ARN-810, to be presented on December 10° at SABCS. ARN-810 is also a SERD that has shown promising Phase 1 data in advanced/metastatic ER positive BC, with early data in only two patients showing some clinical response. However, we believe the competition is manageable as the trial excludes patients with untreated or symptomatic brain metastases, while RAD1901 specifically seeks to target these patients.

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4 December 2014

Figure 1: RDUS income state	ment											
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
Total								82,120	330,415	562,170	717,447	881,759
Income Statement	2013A	1Q14A	2Q14A	3Q14A	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				
Gross Profit	-	-	-	-	-	-	-	65,696	211,452	366,198	475,368	590,700
Operating Expenses						_						
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
Total Operating Expense	67,365	11,856	13,688	16,653	17,626	59,823	87,664	116,838	141,698	168,115	217,893	283,754
EBITDA												
Operating income	(67,365)	(11,856)	(13,688)	(16,653)	(17,626)	(59,823)	(87,664)	(51,142)	69,754	198,083	257,475	306,946
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	3,003	(2,200)	(203)	(002)	(002)	(2,110)	(3,024)	(2,110)	(5,024)	(2,110)	(5,024)	(2,110
Interest (expense) income, net	(2,410)	(399)	(445)	24	24	(796)	(1,544)	(796)	(1,544)	(796)	(1,544)	(796
Accretion of preferred stock	(2,410)	(4,969)	(4,031)		2-1	(100)	(1,011)	(100)	(1,044)	(700)	(1,011)	(130)
Pre-tax income (GAAP)	(60,690)	(19,457)	(16,640)	(17,431)	(18,404)	(71,932)	(95,032)	(54,048)	62,386	195,177	250,107	304,040
Pre-tax income (non-GAAP)	(**,****,	( 2, 2 )	( -77	( , - ,	( 2, 2 ,	( , , , ,	(***,*****)	(- //	,,,,,,		,	,. ,.
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%
TAX TAIL (GAAF)	31 /0	31 /0	31 /0	31 /0	31 /0	31 /0	31 /0	31 /0	31 /0	31 /0	31 /0	37 /6
Net Income (GAAP)	(60,690)	(19,457)	(16,640)	(17,431)	(18,404)	(71,932)	(95,032)	(54,048)	39,303	122,961	157,568	191,545
GAAP EPS (diluted)	(\$3.97)	(\$50.45)	(\$2.22)	(\$0.59)	(\$0.79)	(\$54.05)	(\$3.06)	(\$1.52)	\$1.05	\$3.14	\$3.83	\$4.43
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



4 December 2014

Figure 2: RDUS valuation

Product	Peak Sales (\$MM)	Year	NPV at	Probability Adjustment	Current Value (\$MM)	Scenario probability	Value / Share
abaloparatide							
US	\$822	2022	\$1,299	65%	\$667	100%	\$23
Ex-US - co-promote	\$346	2021	\$403	65%	\$180	50%	\$3
Ex-US - roy alty	\$346	2021	\$193	65%	\$126	50%	\$2
Total abaloparatide					\$847		\$28
Total Product Value					847		\$28
Cash					60		\$2
Total Equity Value					907		\$30
Shares Outstanding (MM)					29		

Risk	-Free Rate	3.0%
Beta		1.8
Risk	Premium	5%
Disc	ount Rate	13%

Source: Canaccord Genuity Estimates



#### **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.



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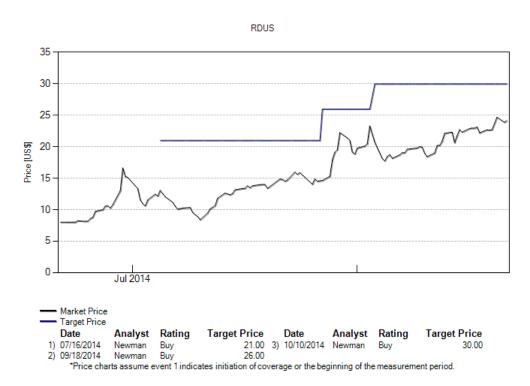
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#### Price Chart:\*



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Coverage Universe				
			IB Clients	
Rating	#	%	%	
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Speculative Buy	53	5.1%	54.7%	

	1041	100.0%	
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\*Total includes stocks that are Under Review

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

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