Radius Health

RDUS : NASDAQ : US$24.60

BUY

Target: US$30.00

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COMPANY STATISTICS:

Forecast Return:	22.0%
Shares Out (M):	29.7
Market Cap (M):	US$731.8
52-week Range:	7.46 - 27.70
Avg. Daily Vol. (000s):	150.1

EARNINGS SUMMARY:

FYE Dec		2013A	2014E	2015E	2016E
Revenue (M):		0.0	0.0	0.0	82.1
EPS:		(3.97)	(54.05)	(3.06)	(1.52)
Revenue (M):	Q1	0.0	0.0A	0.0	-
	Q2	0.0	0.0A	0.0	-
	Q3	0.0	0.0A	0.0	-
	Q4	0.0	0.0	0.0	-
Total		0.0	0.0	0.0	82.1
EPS:	Q1	-	(50.45)A	(0.68)	-
	Q2	-	(2.22)A	(0.88)	-
	Q3	0.00	(0.59)A	(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

RAD-1901 POSITIVE PK/PD DATA IN HEALTHY VOLUNTEERS, COMPETITOR ARN-810 SEES BENEFIT BUT HIGH DIARRHEA

Investment highlights

RAD-1901 shows positive PK/PD data in healthy volunteers

RAD-1901 demonstrated positive estrogen receptor (ER) engagement through FES-PET scans after only 6 days of treatment, with both 200 mg and 500 mg showing an -86% change in SUV at the uterus, affirming ER degrading activity. Importantly, ARN-810 has a similar mechanism of action and showed clinical responses in metastatic breast cancer patients, a positive for RAD-1901.

Clean RAD-1901 safety, CNS penetration in healthy volunteers

After speaking with the primary investigator, RAD-1901 was well tolerated with no grade III toxicity, encouraging as metastatic breast cancer studies begin. Interestingly, MTD has not yet been reached. **Importantly, no diarrhea has been reported.** Additionally, CSF fluid from patients collected detected RAD-1901 in the blood brain barrier, signaling the ability of the drug to penetrate the CNS and possibly become a viable target for patients with brain metastases. We believe these data are encouraging and await further data once this trial is completed by YE14.

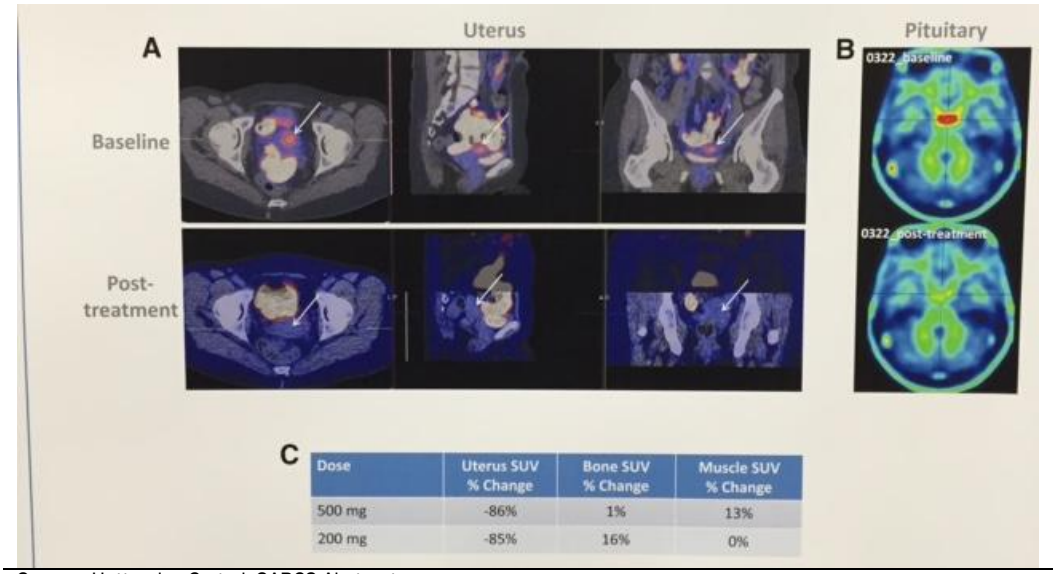
ARN-810 shows 41% clinical benefit rate, but high side effects

Seragon/Genetech's oral selective ER degrader, ARN-810, showed a 41% Clinical Benefit Rate (CBR), and full receptor degradation of the ER in metastatic breast cancer patients, but 63% of patients had diarrhea, and one had a pulmonary embolism, a serious concern. ARN-810 also showed nausea (44%), and one DLT (grade 3 diarrhea) at the highest dose cohort (800 mg). Importantly, pulmonary embolism was deemed a treatment related Serious Adverse Event (SAE). Also, no data has been collected to see if ARN-810 is able to cross the blood brain barrier, which is seen with RAD-1901.

RAD-1901 DEMONSTRATES POSITIVE FES-PET SCAN UPTAKE IN ESTROGEN RECEPTORS

Similar to results previously presented earlier this year, RAD-1901 continues to show positive estrogen receptor (ER) engagement via 18F-estradiol positron emission tomography (FES-PET) in healthy volunteers, confirming the ability of the compound to bind and degrade ER. Additionally, after only 6 days of treatment, there was a -85-86% (near baseline) decrease in uterus standard uptake values (SUV) with minimal change in bone and muscle SUV (controls). We remind investors that ER in healthy volunteers are mainly found in the uterus, and since there are minimum SUV changes in the bone and muscle, the drug is highly specific and potent. We believe this is a positive proof of concept as the trial moves into metastatic breast cancer patients by YE14.

Figure 1: Estrogen receptor imagining using FES-PET tomography



Dose	Uterus SUV % Change	Bone SUV % Change	Muscle SUV % Change
500 mg	-86%	1%	13%
200 mg	-85%	16%	0%

Source: Hattersley G et al. SABCS Abstract

TOLERABLE SAFETY, RAD-1901 DETECTED IN CNS

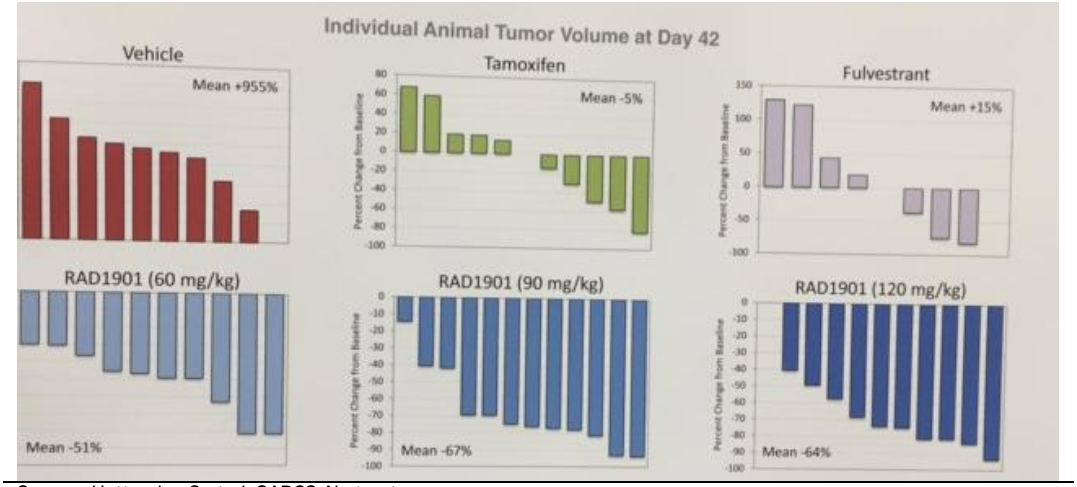
After speaking with the lead investigator, we determined that RAD-1901 was well tolerated at all dose levels and the maximum tolerated dose (MTD) has not been reached. No grade III toxicity has been observed to his knowledge, and importantly, **the trial has not seen any incidence of diarrhea**, which we believe is key as the competitor ARN-810 showed a high of 63% grade I-II diarrhea. When asked if any side effect was more prominent than others, the investigator stated some incidences of grade I-II nausea and headache, though the incidence was low and manageable.

Although not presented in the poster, the investigator stated that the drug was identified in the CSF of healthy volunteers, which we believe is important as this can potentially target the hormone positive metastatic breast cancer patients with brain metastases.

MOUSE XENOGRAFT MODELS SHOW DECREASE OF ESTROGEN-INDUCED TUMOR CELLS

RAD-1901 showed significant decreases in estrogen-induced tumor volumes, with a mean of decrease of -51-64% in all doses, while tamoxifen and fulvestrant only had a -5% and +15% change in tumor volume, respectively. Although the data was in vitro animal models, we believe this higher decrease in tumor volume compared to tamoxifen and fulvestrant demonstrates the potent binding to the ER as well as a conformational change to the receptor itself.

Figure 2: Individual animal tumor volume at day 42



Source: Hattersley G et al. SABCS Abstract

RAD1901 PENETRATING ~$1.4B MARKET IN MBC

Similar to our previous published note, we estimate a total market opportunity of ~$1.4B in patients with hormone receptor positive (HR+) MBC and HR+ BC with brain metastases. Please note that this model is just an assessment of the total market potential for RAD1901. Importantly, we do not currently include revenues for RAD-1901 in our model. However, RAD-1901 represents a second asset for Radius, and addresses a large, ~$1.9B market, which could add meaningful value to the share price assuming activity in metastatic breast cancer patients in 2015.

Figure 3: RAD1901 market opportunity in hormone positive metastatic BC

Total Metastatic BC Patients (HR+/HER2±)	**~65,000 patients**
Front line chemotherapy (40%)	~26,000 patients
Front line endocrine therapy (60%)	~39,000 patients
First line endocrine therapy (74%)	~28,900 patients
Price - $2,500/month	
Duration – 10 months	
Total annual revenue	~$720M
Second line endocrine therapy (19%)	~7,400 patients
Price - $2,500/month	
Duration – 6 months	
Total annual revenue	~$110M
Third line endocrine therapy (7%)	~2,700 patients
Price - $2,500/month	
Duration – 3 months	
Total annual revenue	~$20M
Total market opportunity	**~$850M**

Source: Canaccord Genuity Estimates

We evaluated the opportunity of RAD1901 in the MBC endocrine therapy (ET) landscape. Based on SEER data, there were ~50,000 patients with hormone receptor positive (HR+), HER2- disease and ~15,000 patients with HR+/HER2+ disease in 2013. Detailed epidemiology studies performed by Swallow et al reported 60% of front line metastatic patients receive ET, totaling ~39,000 patients (Swall et al. CMRO; 2014). Studies show that 74% of patients are on first line ET (~28,900 patients, mainly tamoxifen), 19% are on second line ET (~7,400 patients, split between aromatase inhibitors and fulvestrant), and 7% are on third line ET (~2,700 patients). Additionally, as the patient fails one line of therapy, the duration of subsequent therapies decreases from 10 months in first line to 3 months in third line use. Assuming a $2,500 price target per month (fulvestrant is ~$2,000/month), we estimate a market opportunity of ~$850M for all endocrine use in MBC.

Figure 4: Market potential for RAD-1901 in metastatic BC with brain metastases

Total HR+ Metastatic BC with Brain Mets	~12,000 patients
Price - $4,500/month Duration – 10 months	
Total market opportunity	~$540M

Source: Canaccord Genuity Estimates

RAD-1901 has the potential for ~$540M in metastatic breast cancer with brain metastases. SEER data currently estimate ~12,000 patients with hormone positive metastatic BC with brain metastases. We give a higher price target of $4,500 if approved for this indication since the company will probably go for orphan status. Assuming a 10-month duration of survival, we estimate a total market opportunity of ~$540M.

ARN-810 DEMONSTRATES EFFICACY BUT HIGH TOXICITY

ARN-810 displayed high toxicities, although the majorities were grade 1 or 2. The trial saw 63% of patients developing diarrhea, with one patient experiencing a grade 3 dose limiting toxicity (DLT) at the highest 800 mg cohort. Other common side effects included fatigue (46%), nausea (44%), flatulence (24%), anemia (22%), and vomiting (22%). Additionally, one patient experienced a severe treatment-related SAE with pulmonary embolism that occurred after 3 cycles of treatment. We believe the toxicities, although manageable, may decrease patient compliance if the drug is approved and therefore, may negatively affect physician prescribing patterns of this compound. Quality of life in clinical trials was one of the key factors that were highlighted at the San Antonio Breast Cancer Symposium (SABCS), and we are skeptical that ARN-810, although displaying clinical benefit, may actually decrease the QOL of patients with these SAEs. Additionally, the poster presentation states that most diarrhea episodes were managed with intermittent drug holidays, which we find a bit alarming as this can possibly increase the risk of drug resistance.

Figure 5: ARN-810 treatment related side effects in 41 patients

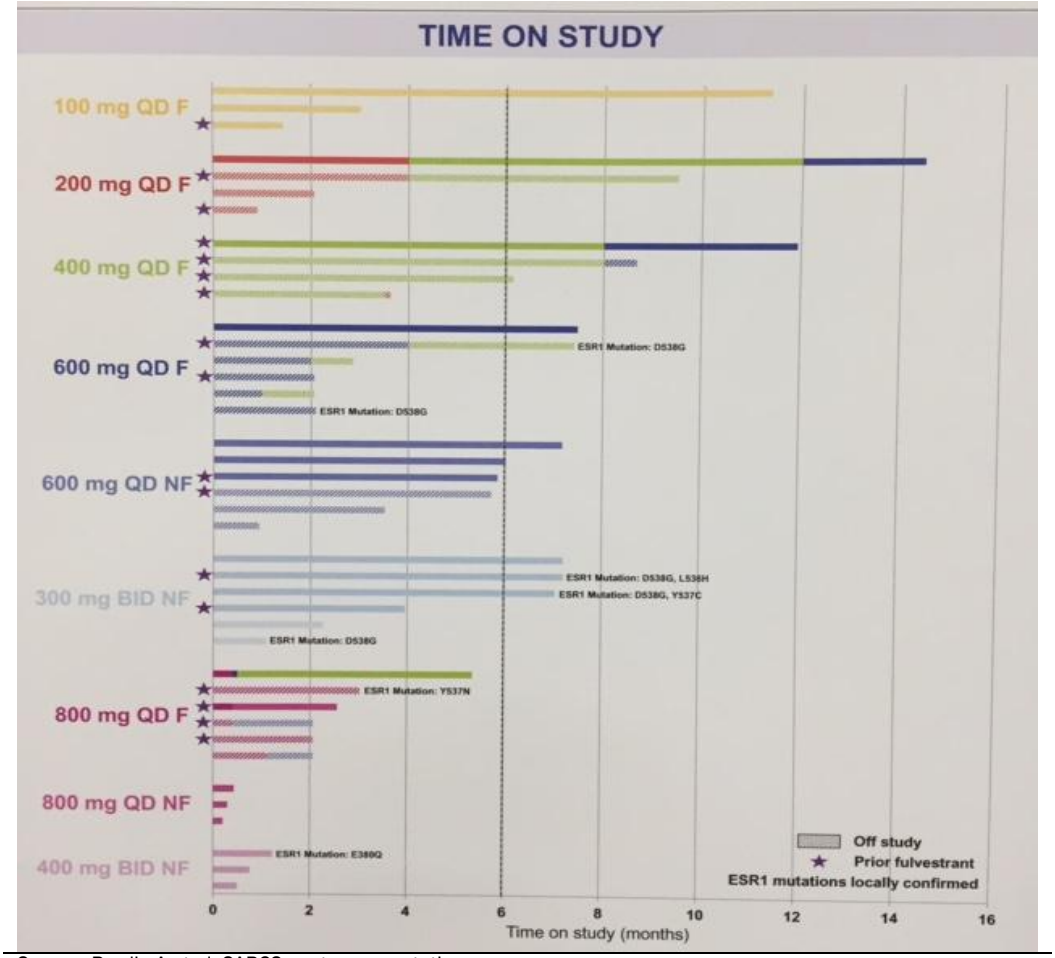
Treatment related adverse events	Grade 1	Grade 2	Grade 3	All Grade
Diarrhea	44%	17%	2%	63%
Fatigue	34%	12%	0%	46%
Nausea	32%	12%	0%	44%
Flatulence	19%	5%	0%	24%
Anemia	19%	2%	0%	22%
Vomiting	15%	7%	0%	22%
Decreased appetite	19%	0%	0%	19%
Dyspepsia	17%	2%	0%	19%
ALT increased	15%	2%	0%	17%
Abdominal pain	12%	2%	0%	15%
AST increased	15%	0%	0%	15%

Source: Bardia A et al. SABCS poster presentation

41% CLINICAL BENEFIT RATE AND 95% FES PET DEGRADATION AFFIRMS PROOF OF CONCEPT IN AR+, POSITIVE FOR RDUS

ARN-810 demonstrated a 41% clinical benefit rate (CBR) in postmenopausal women with metastatic estrogen receptor positive (ER+) HER2- breast cancer, affirming the mechanism of action of selective estrogen degredators in actual human patients. The presentation does not break down the CBR between CR/PR/SD, although the investigators feel confident in the results since patients have been on study trial for almost 14 months and continuing. Additionally, 34% of patients had failed faslodex. Although we do not currently know if these patients had any clinical benefit with ARN-810, we believe that response in these patients may confirm that these next generation SERDs can have a more potent inhibition of the ER with potential conformational change of the receptor itself.

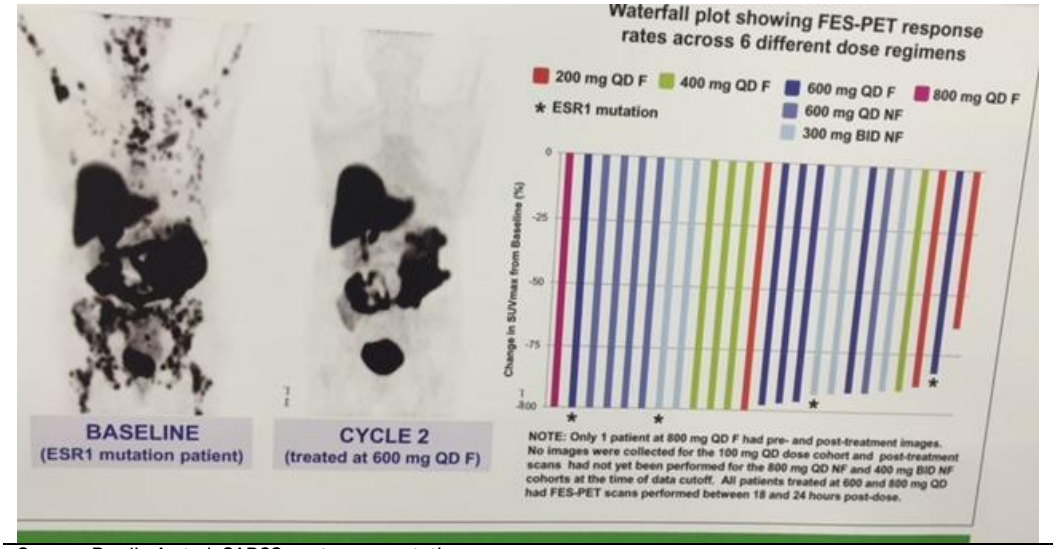
Figure 6: ARN-810 time on study drug by dose



Source: Bardia A et al. SABCS poster presentation

Additionally, the waterfall plot below shows that across all dosing regimens, there was a near complete reduction in FES uptake in about 95% of patients, including 2 patients with ESR1 mutations. This suggests that ARN-810 exhibits greater inhibition of ER than previously reported fulvestrant and demonstrates receptor saturation and/or degradation. These results did translate to clinical benefits with a 41% CBR, which we feel is a positive for RDUS as similar pharmacodynamics results were presented as stated previously. Moreover, no data has been presented to see if ARN-810 can cross the blood brain barrier, since the current trial excludes patients with brain metastases. We believe the positive CSF finding of RAD-1901 allows the compound to penetrate the metastatic breast cancer brain metastases market, which we currently a ~$540M market, driving revenue growth for the company substantially.

Figure 7: FES-PET response rate at 28 days



Source: Bardia A et al. SABCS poster presentation

Figure 8: RDUS income statement

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	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			(203)									
Interest (expense) income, net	(2,410)	(399)	(445)	24	24	(796)	(1,544)	(796)	(1,544)	(796)	(1,544)	(796)
Accretion of preferred stock		(4,969)	(4,031)									
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)												
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%
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

Figure 9: RDUS valuation

Product	Peak Sales ($MM)	Year	NPV at launch	Probability Adjustment	Current Value ($MM)	Scenario probability	Value / Share
abaloparatide							
US	$822	2022	$1,299	65%	$669	100%	$23
Ex-US - co-promote	$346	2021	$403	65%	$181	50%	$3
Ex-US - royalty	$346	2021	$193	65%	$126	50%	$2
Total abaloparatide					**$849**		**$28**
Total Product Value					849		$28
Cash					60		$2
Total Equity Value					**909**		**$30**
Shares Outstanding (MM)					29		

Risk-Free Rate	3.0%
Beta	1.8
Risk Premium	5%
Discount 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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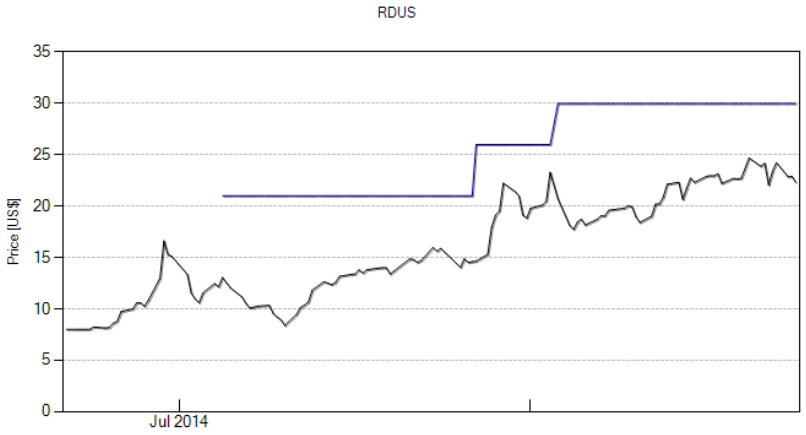
Site Visit: An analyst has visited Radius Health's material operations in Cambridge, Massachusetts. No payment or reimbursement was received from the issuer for the related travel costs.

Price Chart:*



	Date	Analyst	Rating	Target Price		Date	Analyst	Rating	Target Price
1)	07/16/2014	Newman	Buy	21.00	3)	10/10/2014	Newman	Buy	30.00
2)	09/18/2014	Newman	Buy	26.00					

*Price charts assume event 1 indicates initiation of coverage or the beginning of the measurement period.

Distribution of Ratings:
Global Stock Ratings
(as of 1 October 2014)

	Coverage Universe		IB Clients
Rating	#	%	%
Buy	627	60.2%	36.7%
Speculative Buy	53	5.1%	54.7%
Hold	317	30.5%	13.9%
Sell	43	4.1%	2.3%
	1041	100.0%	

*Total includes stocks that are Under Review

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

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