

## COMPANY NOTE

Target | Estimate Change

USA | Healthcare | Biotechnology

November 11, 2014

# Jefferies

## Radius Health (RDUS) Topline Ph3 Data for Abaloparatide-SC on Track for Late-December

### Key Takeaway

**With topline Ph3 data for lead product abaloparatide-SC in osteoporosis by YE14, we continue to view Ph3 success as highly likely (primary endpoint of new vertebral fracture reduction vs. placebo). More importantly, Ph2 & long-term monkey data suggest potential for superior efficacy in non-vertebral fracture reduction in Ph3 (vs. Forteo; ~\$1.25B in 2013 sales), providing significant upside potential.**

**Slightly wider 3Q14 net loss of \$17.4M vs. our loss estimate of ~\$15.2M.** There was no revenue and OpEx of \$16.7M was ~18% higher (vs. ours of \$14.1M), including R&D of ~\$13.8M (vs. ours of \$11M) and G&A of \$2.8M (vs. ours of \$3.1M). We estimate RDUS' cash at end-3Q14 of \$69M sufficient into ~2016.

**Topline Ph3 data for abaloparatide-SC (18-month fracture data) in osteoporosis on track to be reported in late-December.** RDUS noted last patient visit in the Ph3 occurred in October, with all patients currently enrolled in the 6-months extension study (potential data in ~2Q15). We continue to view highly likely Ph3 success (primary endpoint of new vertebral fracture reduction vs. placebo at 18mo) for regulatory approval; advantages of abaloparatide-SC vs. Forteo in non-vertebral fracture risk reduction is key to commercial success (Forteo, ~\$1.25B in 2013 sales).

**RDUS to begin Ph2b for RAD1901 in vasomotor symptoms in 2H15 (vs. previously seeking a partnership).** Ph2b is designed to define a minimal effective dose (including 10mg and lower daily doses) in pts with vasomotor symptoms. For breast cancer indication (higher dose RAD1901), RAD1901 is currently in Ph1 in healthy subjects to determine MTD, with Ph1b in ER+ BCBM pts expected to begin in 4Q14 in the EU, and protocol for U.S. Ph1b study under development.

**Upcoming events for RDUS include:** (1) Ph1 data for RAD1901 at San Antonio Breast Cancer Symposium, 12/9-12/13/14; (2) topline Ph3 data for abaloparatide-SC in late-Dec. 2014 (18-month fracture risk reduction data); (3) initiation of Ph1b for RAD1901 in ER-positive BCBM (EU trial) by YE14; (4) abaloparatide-SC 24-months data (6-months extension from the Ph3) in 2Q15; (5) potential U.S./EU regulatory filings for abaloparatide-SC in ~mid-2015; and (6) Ph2b for RAD1901 in vasomotor symptoms to begin in 2H15.

### Valuation/Risks

Our \$26 PT is based on an NPV analysis of abaloparatide-SC U.S./EU sales/royalty. Risks for RDUS are primarily on abaloparatide-SC, including: (1) clinical/regulatory delays/failure; (2) slow commercial uptake and/or competition and (3) general industry risks.

USD	Prev.	2014E	Prev.	2015E	Prev.	2016E	Prev.	2017E
Rev. (MM)	--	0.0	--	0.0	--	31.5	--	26.3
<b>EPS</b>								
Mar	--	(50.45)A	--	(0.50)	--	--	--	--
Jun	--	(2.22)A	--	(0.50)	--	--	--	--
Sep	(0.51)	(0.59)A	--	(0.47)	--	--	--	--
Dec	--	(0.53)	--	(0.44)	--	--	--	--
FY Dec	(3.11)	(3.17)	(1.50)	(1.91)	(1.16)	(1.33)	(1.76)	(1.77)

EPS: RDUS completed its IPO in 2Q14

**BUY**

Price target \$26.00

(from \$17.00)

Price \$22.32

### Financial Summary

Book Value (MM):	\$23.4
Book Value/Share:	\$0.79
Net Debt (MM):	(\$68.5)
Long-Term Debt (MM):	\$0.0
Cash/Share:	\$2.31
Cash (MM):	\$68.5

### Market Data

52 Week Range:	\$24.93 - \$7.46
Total Entprs. Value (MM):	\$594.4
Market Cap. (MM):	\$662.9
Shares Out. (MM):	29.7
Float (MM):	9.6
Avg. Daily Vol.:	107,014

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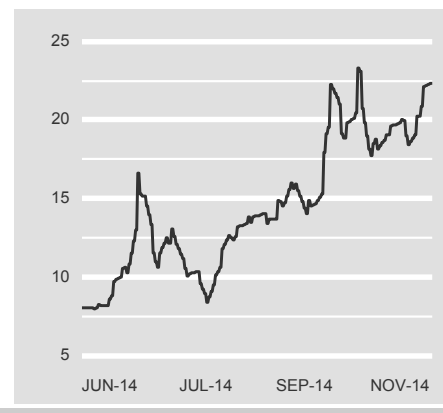
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### Price Performance



## Scenarios

## Target Investment Thesis

- Phase 3 data for lead product abaloparatide-SC in osteoporosis is expected in late-December 2014
- RDUS' cash at end-3Q14 of ~\$69M is roughly sufficient into 2016
- Our NPV analysis puts a target price of \$26 per share including abaloparatide-SC (~\$15/sh for U.S. sales and ~\$5/sh for EU sales) and ~\$6/sh for RAD1901 combined U.S./EU sales

## Upside Scenario

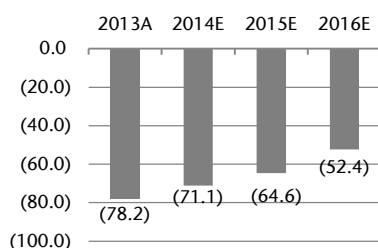
- Phase 3 data for abaloparatide-SC showing superiority vs. Forteo in non-vertebral fracture risk reduction
- Better-than-expected sales of abaloparatide-SC in osteoporosis
- On 100% probability of success for abaloparatide-SC in U.S./EU and 50% higher sales vs. our estimates, our NPV analysis pegs a fair value for RDUS shares at \$40

## Downside Scenario

- Clinical/regulatory failure of abaloparatide-SC
- Slower than expected commercial uptake of abaloparatide-SC
- Clinical failure of RAD-1901 in BCBM
- On 50% lower abaloparatide-SC sales in U.S./EU vs. our estimates, our NPV analysis pegs a fair value for RDUS shares at \$16

## Long Term Analysis

## Net Income/Loss (\$ in MM)



Source: FactSet, Jefferies estimates

## Long Term Financial Model Drivers

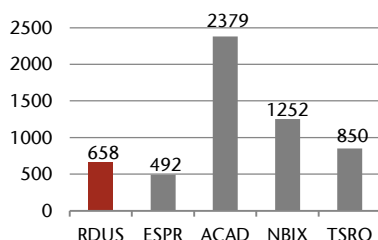
<b>LT revenue CAGR ('17-'22)</b>	<b>72%</b>
Organic Revenue Growth	<b>72%</b>
Acquisition Contribution	<b>0%</b>
Gross Margin Expansion	<b>N/A</b>

## Other Considerations

For lead abaloparatide-SC, we view achieving primary endpoint of fracture risk reduction vs. placebo as highly likely (data in 12/14). However, key to commercial success lies in abaloparatide-SC demonstrating superiority vs. Forteo (~\$1.25B in 2013 sales) for BMD increases (numerical increases shown in Phase 2) and more importantly for non-vertebral fracture risk reduction, providing significant upside potential.

## Peer Group

## Enterprise Value (\$ in MM)



Source: FactSet, Jefferies estimates

## Recommendation / Price Target

Ticker	Rec.	PT
<b>RDUS</b>	<b>Buy</b>	<b>\$26</b>
ESPR	NC	N/A
ACAD	Buy	\$38
NBIX	Buy	\$22
TSRO	Buy	\$40
CLVS	NC	N/A

## Catalysts

- Ph1 data for RAD1901 at San Antonio Breast Cancer Symposium, 12/9-12/13/14
- Topline 18-months Phase 3 fracture risk reduction data for abaloparatide-SC in late-December 2014
- Initiation of Ph1b for RAD1901 in ER-positive BCBM (EU trial) by YE14
- Abaloparatide-SC 24-months extension study data in 2Q15

## Company Description

Radius Health, Inc., IPOed on 6/5/14, is a biopharmaceutical company focused on developing therapies for osteoporosis and other endocrine diseases. The company's lead product is abaloparatide-SC (BA058), a novel synthetic peptide analog of parathyroid hormone-related protein (PTHrP), with topline data from ongoing Phase 3 for osteoporosis expected in December 2014. Additional pipeline products include a transdermal (TD) formulation of abaloparatide, abaloparatide-TD; RAD1901, an oral selective estrogen receptor down-regulator/degrader (SERD) for the treatment of breast cancer brain metastases (BCBM) and vasomotor symptoms; and RAD140, a non-steroidal selective androgen receptor modulator. Radius was founded in 2003 and is headquartered in Cambridge, Massachusetts.

**Increasing our PT to \$26 (from \$17) on now including RAD1901 in our valuation, increased probability of success for abaloparatide-SC, and time lapse of discount years.** For RAD1901, in its ongoing Phase 1 MTD study, RDUS presented initial proof-of-concept data on 8/28/14, showing that RAD1901 suppresses baseline estrogen receptor (ER) imaging sites in healthy volunteers, as assessed by PET (positron emission tomography) imaging. With first human data, albeit very early in proof-of-concept stage, we are increasing our peak penetration for RAD1901 to 20% (from 10% previously); forecasting peak U.S./EU combined RAD1901 sales potential of ~\$470M in 2025 (from ~\$235M previously), and including RAD1901 in our valuation.

For abaloparatide-SC currently in Phase 3 for osteoporosis, our recent endocrinologists discussions gave us increased confidence in the likelihood of Phase 3 success for abaloparatide-SC showing superiority vs. placebo based on, thus, we are increasing probability of clinical success to 90% (vs. 85% previously).

Our \$26 PT is based on NPV analysis of ~\$15/sh (from \$12/sh previously) for abaloparatide-SC U.S. sales in osteoporosis (90% [from 85%] probability adjusted peak sales of ~\$308M in 2027) and ~\$5/sh (unchanged) for abaloparatide-SC EU royalties in osteoporosis (90% [from 85%] probability adjusted peak royalties of ~\$51M in 2027), and ~\$6/sh for RAD1901 U.S./EU sales in ER+ BCBM (not previously included in our valuation; 50% probability-adjusted peak sales of \$470M in 2025), discounting at an annual rate of 11%.

**Chart 1: Radius Health's Product Pipeline**

Product	Description	Indication	Status	Marketing rights	Patent expiry
Abaloparatide	Synthetic peptide analog of parathyroid hormone-related protein (PTHrP)	Fracture prevention in osteoporosis; subcutaneous (SC) formulation	<p>Top-line Ph3 (18-mo) data in late-December 2014, with NDA/MAA filing in ~mid-2015 (including 24 mo fracture data) &amp; U.S./EU approval in 2016/2017, respectively</p> <p>Ph3 randomized (1:1:1) ACTIVE study (begun in 4/11, with enrollment completed in 3/13) comparing 1x daily abaloparatide-SC (80ug) vs. Forteo (20ug) vs. placebo in PMO women (n=2,463) with primary endpoint of new vertebral fractures vs. placebo at 18 mo and secondary endpoints including BMD of lumbar spine, hip, and femoral neck, non-vertebral fractures, and # of hypercalcemic events; enrollment completed in 3/13; last pts last visit in 10/14</p> <p>6-months extension study begun in 10/12 for pts enrolled in Ph3 (n=1200); pts in either abaloparatide-SC and placebo arms to receive alendronate (generic Fosamax), with endpoints including vertebral fractures at 24 mo and safety; potential data in 2Q15</p>	Radius (worldwide ex-Japan, ex-France, with Ipsen co-promote in France); Ipsen (Japan)	In U.S./EU, CoM expires on 3/29/16 (potential Hatch-Waxman extension into 2021 in U.S.); formulation patent expires on 11/8/27 & method of treatment patent expires on 3/26/28 in the U.S.; pending method of treatment patent expires on 10/3/27 in EU
		Fracture prevention in osteoporosis; transdermal (TD) patch	Ph2 randomized, double-blind study comparing three doses of 1x daily abaloparatide-TD (50ug, 100ug, 150ug) vs. abaloparatide-SC (80ug) vs. placebo (n=250; primary endpoint of % increase in BMD at 6mo from baseline) announced in 1/14 with statistically significant increases in both BMD at lumbar spine & hip over placebo for 100ug and 150ug doses; currently optimizing transdermal patch dose & formulation to achieve comparable PK profile to abaloparatide-SC; if comparable, upon potential approval of SC version, planning single Ph3 non-inferiority bridging study comparing abaloparatide-SC vs. abaloparatide-TD, with endpoints including lumbar spine BMD at 12 mo	Radius	In U.S./EU, CoM expires on 3/29/16 (potential Hatch-Waxman extension into 2021 in U.S.); pending patents on microneedle application expire in 2032
RAD1901	Oral selective estrogen receptor (ER-alpha) down-regulator (SERD)/selective estrogen receptor modulator (SERM)	ER-positive breast cancer with brain metastases (high dose); vasomotor symptoms (low dose)	<p>Ph1b in ER-positive mBC with brain metastases expected to begin in 4Q14 (EU mBC study) and US Phase 1b mBC protocol under development, with Phase 1b data by ASCO 2015; first part of two-part Phase 1 study in healthy subjects to determine MTD began in 2Q14 with data in 4Q14 at San Antonio Breast Cancer Symposium, 12/9-12/13/14 (vs. ~3Q14 previously)</p> <p>Ph2b to define minimal effective dose (including 10mg and lower daily doses) in vasomotor symptoms to begin in 2H15</p>	Radius (worldwide ex-Japan); Eisai (Japan)	In U.S., two CoM patents expire on 12/25/23 and 8/18/26; in EU, pending patents expire in 2023
RAD140	Non-steroidal selective androgen receptor modulator	N/A	Preclinic	Radius	In U.S., pending CoM expires in 2029

PMO=post-menopausal osteoporosis; BMD=bone mineral density; PK=pharmacokinetics

Source: Company reports and Jefferies

**Radius Health (RDUS)**  
**Income Statement**  
(\$ in thousands except per share)

	2013	1Q14	2Q14	3Q14	4Q14E	2014E	1Q15E	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenues																					
Abaloparatide-SC for PMO (U.S.)												-	26,299	88,123	152,791	199,465	243,168	252,968	263,162	273,768	284,801
Growth y/y														235%	73%	31%	22%	4%	4%	4%	4%
Growth q/q																					
Royalty for abaloparatide-SC for PMO (EU)												-		5,418	17,794	30,241	38,697	46,241	47,152	48,081	49,028
Growth y/y															228%	70%	28%	19%	2%	2%	2%
RAD1901 for ER+ BCBM (U.S./EU)																18,152	91,854	196,339	299,680	396,457	470,131
Growth y/y																	406%	114%	53%	32%	19%
Other revenues												31,500									
Total Revenues	-	-	-	-	-	-	-	-	-	-	-	31,500	26,299	93,541	170,585	247,858	373,719	495,548	609,995	718,306	803,960
% growth y/y														255.7%	82.4%	45.3%	50.8%	32.6%	23.1%	17.8%	11.9%
Expenses																					
Cost of Goods Sold		-	-	-	-	-	-	-	-	-	-	-	4,734	13,219	21,391	28,109	40,203	53,917	70,538	84,392	95,293
% gross margin (Including royalties to Ipsen & Eisai)													82.0%	85.0%	86.0%	85.9%	83.5%	78.7%	73.2%	69.2%	66.5%
R&D	60,536	9,717	10,618	13,817	13,974	48,126	13,000	12,500	11,000	9,220	45,720	34,290	30,861	30,861	32,404	34,996	37,796	40,820	44,085	47,612	51,421
% growth y/y	10.1%					-20.5%					-5.0%	-25.0%	-10.0%	0.0%	5.0%	8.0%	8.0%	8.0%	8.0%	8.0%	8.0%
% of total revenues														33.0%	19.0%	14.1%	10.1%	8.2%	7.2%	6.6%	6.4%
SG&A	6,829	2,139	3,070	2,836	2,854	10,899	3,000	3,600	4,300	5,013	15,913	35,803	48,335	53,168	63,802	73,372	80,709	87,166	94,139	101,670	109,804
% growth y/y	-27.9%					59.6%					46.0%	125.0%	35.0%	10.0%	20.0%	15.0%	10.0%	8.0%	8.0%	8.0%	8.0%
% of total revenues													183.8%	56.8%	37.4%	29.6%	21.6%	17.6%	15.4%	14.2%	13.7%
Restructuring cost																					
Total Expenses	67,365	11,856	13,688	16,653	16,828	59,025	16,000	16,100	15,300	14,232	61,632	70,093	83,929	97,248	117,597	136,477	158,708	181,902	208,762	233,674	256,518
Income (loss) from Operations (EBIT)	(67,365)	(11,856)	(13,688)	(16,653)	(16,828)	(59,025)	(16,000)	(16,100)	(15,300)	(14,232)	(61,632)	(38,593)	(57,631)	(3,707)	52,989	111,381	215,011	313,645	401,232	484,632	547,442
% growth y/y																110.2%	93.0%	45.9%	27.9%	20.8%	13.0%
Operating margin															31.1%	44.9%	57.5%	63.3%	65.8%	67.5%	68.1%
Other Income (Expense), Net	6,675	(2,632)	1,079	(767)	(770)	(3,090)	(750)	(750)	(750)	(750)	(3,000)	(13,800)	(12,600)	(6,300)	500	1,000	2,000	3,000	4,000	5,000	6,000
Earnings (Loss) Before Taxes	(60,690)	(14,488)	(12,609)	(17,420)	(17,598)	(62,115)	(16,750)	(16,850)	(16,050)	(14,982)	(64,632)	(52,393)	(70,231)	(10,007)	53,489	112,381	217,011	316,645	405,232	489,632	553,442
Provision for Taxes	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	5,619	21,701	47,497	81,046	122,408	138,361
Tax Rate															0.0%	5.0%	10.0%	15.0%	20.0%	25.0%	25.0%
Net Income (Loss)	(60,690)	(14,488)	(12,609)	(17,420)	(17,598)	(62,115)	(16,750)	(16,850)	(16,050)	(14,982)	(64,632)	(52,393)	(70,231)	(10,007)	53,489	106,762	195,310	269,148	324,186	367,224	415,082
Extinguishment of preferred stock																					
Accretion of preferred stock	(17,471)	(4,969)	(4,031)			(9,000)															
Earnings to preferred stockholders																					
Net Income (Loss) to Common Stockholders	(78,161)	(19,457)	(16,640)	(17,420)	(17,598)	(71,115)	(16,750)	(16,850)	(16,050)	(14,982)	(64,632)	(52,393)	(70,231)	(10,007)	53,489	106,762	195,310	269,148	324,186	367,224	415,082
EPS (LPS) - Basic	(203.91)	(50.45)	(2.22)	(0.59)	(0.53)	(3.17)	(0.50)	(0.50)	(0.47)	(0.44)	(1.91)	(1.33)	(1.77)	(0.25)	1.32	2.61	4.72	6.44	7.68	8.62	9.64
EPS (LPS) - Diluted	(203.91)	(50.45)	(2.22)	(0.59)	(0.53)	(3.17)	(0.50)	(0.50)	(0.47)	(0.44)	(1.91)	(1.33)	(1.77)	(0.25)	1.17	2.32	4.20	5.74	6.84	7.67	8.59
% growth y/y (diluted)																					
Shares - Basic	383	386	7,500	29,746	33,173	22,466	33,505	33,672	33,841	34,010	33,757	39,350	39,743	40,141	40,542	40,948	41,357	41,771	42,188	42,610	43,036
Shares - Diluted	383	386	7,500	29,746	33,173	22,466	33,505	33,672	33,841	34,010	33,757	39,350	39,743	40,141	45,542	45,998	46,458	46,922	47,391	47,865	48,344
Cash, Cash Equivalents & Investments	12,303	29,558	79,021	68,514	109,216	109,216	92,466	75,616	59,566	44,583	44,583	86,190	15,959	5,953	59,441	166,203	361,513	630,661	954,847	1,322,071	1,737,153

Source: Jefferies and Company financials

## Company Description

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The expected total return (price appreciation plus yield) for Buy rated stocks with an average stock price consistently below \$10 is 20% or more within a 12-month period as these companies are typically more volatile than the overall stock market. For Hold rated stocks with an average stock price consistently below \$10, the expected total return (price appreciation plus yield) is plus or minus 20% within a 12-month period. For Underperform

rated stocks with an average stock price consistently below \$10, the expected total return (price appreciation plus yield) is minus 20% within a 12-month period.

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NC - Not covered. Jefferies does not cover this company.

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Monitor - Describes stocks whose company fundamentals and financials are being monitored, and for which no financial projections or opinions on the investment merits of the company are provided.

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## Risk which may impede the achievement of our Price Target

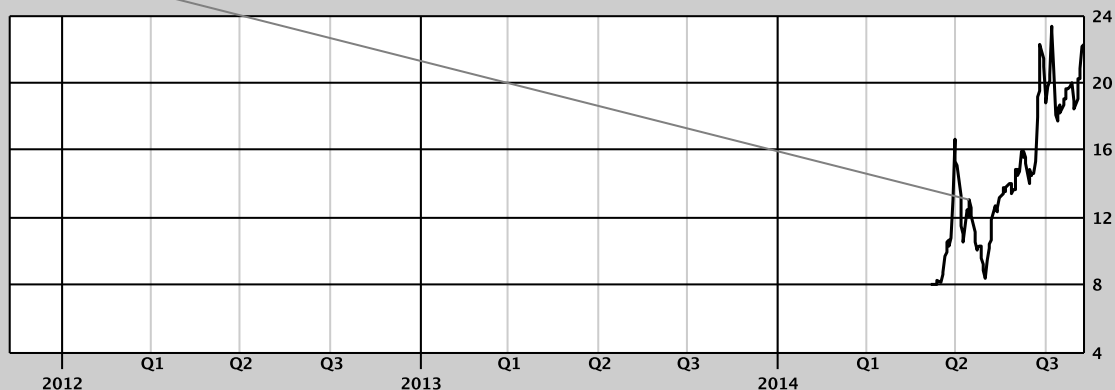
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## Other Companies Mentioned in This Report

- ACADIA Pharmaceuticals Inc. (ACAD: \$28.21, BUY)
- Neurocrine Biosciences (NBIX: \$18.98, BUY)
- Radius Health, Inc. (RDUS: \$22.32, BUY)
- Tesaro, Inc. (TSRO: \$28.28, BUY)

**Rating and Price Target History for: Radius Health, Inc. (RDUS) as of 11-10-2014**

07/16/14  
I:B:\$17



**Rating and Price Target History for: ACADIA Pharmaceuticals Inc. (ACAD) as of 11-10-2014**

03/18/13  
I:B:\$13

04/12/13  
B:\$18

08/06/13  
B:\$26

03/03/14  
B:\$38





## Rating and Price Target History for: Neurocrine Biosciences (NBIX) as of 11-10-2014



## Rating and Price Target History for: Tesaro, Inc. (TSRO) as of 11-10-2014



## Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos.	
			Count	Percent
BUY	1014	52.16%	267	26.33%
HOLD	790	40.64%	142	17.97%
UNDERPERFORM	140	7.20%	5	3.57%

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