

## US Equity Research

2 February 2015

## BUY

unchanged

PRICE TARGET US\$70.00

unchanged

Price (1-Feb) US\$48.19

Ticker RDUS-NASDAQ

52-Week Range (US\$): 7.46 - 48.09  
 Avg Daily Vol (M) : 214.3  
 Shares Out. (M) : 29.7  
 Market Cap (US\$M): 1,433

FYE Dec	2013A	2014E	2015E	2016E
Revenue (US\$M)	0.0	0.0	0.0	82.1
EPS Adj&Dil (US\$)	(3.97)	(54.05)	(3.06)	(1.52)

Quarterly Revenue	Q1	Q2	Q3	Q4
2013A	-	-	-	-
2014E	0.0A	0.0A	0.0A	0.0
2015E	0.0	0.0	0.0	0.0
2016E	-	-	-	-

Quarterly EPS Adj&Dil	Q1	Q2	Q3	Q4
2013A	-	-	-	-
2014E	(50.45)A	(2.22)A	(0.59)A	(0.79)
2015E	(0.68)	(0.88)	(0.75)	(0.75)
2016E	-	-	-	-



Radius is a biotechnology company focused on drugs for endocrine disorders, including osteoporosis.

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## Company Update

## Minimal generic Forteo risk for abaloparatide based on FDA analysis

## Generic Forteo filing unlikely, none after 13 years on market

We do not expect a generic filing or approval for Forteo in the near future due to its complicated *E. Coli* derived peptide formulation and our review of generic challenges for other FDA-approved peptide drugs. No ANDA filings have ever surfaced for Forteo, despite being approved since 2002 without NCE status, likely due to its peptide formulation from *E. Coli*. Therefore, we do not expect to see generic competition against Forteo, until at least the final patent expires in 2025, and perhaps later, which is a positive for Abaloparatide.

## FDA analysis suggests high barrier for generic peptide drugs

Our deep dive analysis of FDA approved branded peptides (n=43) shows that only 23% (n=10) had ANDA filings, and only 14% (n=5) had generic approvals, reflecting the difficulty in producing bioequivalent peptides by generics companies. Additionally, 6 out of the 10 ANDA filings were synthetic peptides, which we believe are easier to produce than recombinant DNA from fermented bacteria/yeasts.

Recombinant therapeutics in *E. Coli* difficult to manufacture

Forteo is currently produced via *E. Coli*, which has likely deterred most generics companies due to complexity and cost, in our view. Interestingly, we found no generics approved for peptides produced via *E. Coli* (Glucagon, Insulin, Somavert and Gattex), and no ANDA filings. We believe this is attributed to 1) regulatory requirements for large scale industrial production with *E. Coli*, including FDA guidelines and local Biosafety Authority; 2) high cost of peptide production via fermentation; and 3) lack of specific FDA guidance for demonstrating bioequivalence to Forteo. We believe it is unlikely that an ANDA filing via paragraph 4 will surface before final patent expiration for Forteo in 2025.

## Maintain \$800M peak sales estimate for Abaloparatide, expect approval mid-2016

We estimate peak US sales of ~\$800M for Forteo by 2022 and assume an on time FDA approval by mid-2016. Our estimate assumes 3.9 million patients by 2022, a pricing of ~\$2,000 per month for the drug, and a conservative ~1.9% market share with 50% drug adherence to reach our estimate. Additionally, the company is also working on a transdermal microneedle patch for potential use as a short wear-time formulation, which could be attractive to both patients and physicians if PK analysis reflects similar results, specifically AUC. We await further details from the company in rolling out the final transdermal patch configuration, possibly sometime in 2015, as a potential value driver for the stock.

**Figure 1: History of Peptides and ANDA filing, Tentative Approvals, and Full Approvals**

Name	Brand name	FDA approval date	Exclusivity		Description	ANDA filing?	Time till ANDA Filing (YRS)	tentative approval?	Time till Tentative approval (YRS)	full approval?	Company	Approval Date / Rating		Time till Full approval (YRS)
			Type	Expiration										
<a href="#">Aliskiren</a>	<a href="#">Tekturna</a>	3/5/2007	NCE	3/5/2012	non-peptide analogue	12/13/2013	6.8							
<a href="#">Bivalirudin</a>	<a href="#">Angiomax</a>	12/15/2000	NCE	12/15/2005	Synthetic peptide	9/1/2009	8.7	9/23/2013	12.8					
<a href="#">Choriogonadotropin alfa</a>	<a href="#">Ovidrel</a>	9/20/2000	new dosage form		Recombinant human Chorionic Gonadotropin									
<a href="#">Corticotropin</a>	<a href="#">Acthar</a>	7/3/1950	NCE	n/a	sterile preparation of "highly purified" adrenocorticotrophic hormone									
<a href="#">Cosyntropin</a>	<a href="#">Cortrosyn</a>	4/22/1970	NCE	n/a	Synthetic polypeptide	yes				yes	Sandoz Mylan	6/29/2012 12/23/2009	AP AP	42.2 39.7
<a href="#">Daptomycin</a>	<a href="#">Cubicin</a>	9/12/2003	NCE	9/12/2008	lipopeptide antibacteria from fermented <i>Streptomyces roseosporus</i>	11/19/2008	5.2	3/15/2013	9.5	yes	Hospira	9/12/2014	AP	11.0
<a href="#">Entuviride</a>	<a href="#">Fuzeon</a>	3/13/2003	NCE	3/13/2008	Synthetic peptide									
<a href="#">Eptifibatide</a>	<a href="#">Integrilin</a>	5/18/1998	NCE	5/18/2003	Synthetic peptide	9/30/2008	10.4							
<a href="#">Exenatide</a>	<a href="#">Byetta</a>	4/28/2005	NCE	4/28/2010	Synthetic peptide	6/11/2014	9.1							
<a href="#">Exenatide</a>	<a href="#">Bydureon</a>	1/27/2012	NCE	1/27/2017	Synthetic peptide	6/11/2014	2.4							
<a href="#">Fibrinolysin</a>	<a href="#">ELASE-CHLOROMYCETIN</a>	4/1/1964	NCE	n/a	Enzyme from bovine plasma									
<a href="#">Follitropin Alpha/Beta</a>	<a href="#">Gonal</a>	9/29/1997	NCE	9/29/2002	human follicle stimulating hormone (FSH) preparation of recombinant DNA origin - chinese hamster ovary cells			2/26/2002	4.4					
<a href="#">Glatiramer Acetate</a>	<a href="#">Copaxone</a>	12/20/1996	NCE	12/20/2001	synthetic polypeptides	12/27/2007	11.0							
<a href="#">Glucagon recombinant</a>	<a href="#">Glucagon</a>	9/11/1998	new dosage form		E. Coli polypeptide hormone									
<a href="#">Hyaluronidase</a>	<a href="#">Amphadase</a>	10/26/2004	NCE	10/26/2009	purified bovine testicular hyaluronidase, a protein enzyme									
<a href="#">Insulin</a>	<a href="#">Atezza</a>	6/27/2014	new formulation		E. Coli polypeptide hormone									
<a href="#">Insulin Glusine recombinant</a>	<a href="#">Apidra</a>	4/16/2004	NCE	4/16/2009	E. Coli polypeptide hormone									
<a href="#">Insulin Glargine</a>	<a href="#">Basaglar</a>	8/18/2014	new formulation		E. Coli polypeptide hormone									
<a href="#">Insulin recombinant human</a>	<a href="#">Exubera</a>	1/27/2006	new dosage form		E. Coli polypeptide hormone									
<a href="#">Insulin Lispro</a>	<a href="#">Humalog</a>	6/14/1996	NCE		E. Coli polypeptide hormone									
<a href="#">Insulin recombinant human</a>	<a href="#">Humulin BR</a>	4/28/1986	new dosage form		E. Coli polypeptide hormone									
<a href="#">Insulin glargine recombinant</a>	<a href="#">Lantus</a>	4/20/2000	NCE	4/20/2005	E. Coli polypeptide hormone									
<a href="#">Insulin recombinant human</a>	<a href="#">Novolin R</a>	6/25/1991	new formulation		E. Coli polypeptide hormone									
<a href="#">Insulin Aspart Recombinant</a>	<a href="#">Novolog</a>	6/7/2000	NCE	6/7/2005	E. Coli polypeptide hormone									

Source: FDA.gov

Figure 2: History of Peptides and ANDA filing, Tentative Approvals, and Full Approvals

Name	Brand name	FDA approval date	Exclusivity		Description	ANDA filing?	Time till ANDA Filing (YRS)	tentative approval?	Time till Tentative approval (YRS)	full approval?	Company	Approval Date / Rating		Time till Full approval (YRS)
			Type	Expiration										
<a href="#">Leuprolide acetate</a>	<a href="#">Lupron</a>	3/30/1995	new formulation		synthetic nonapeptide analog of naturally occurring gonadotropin releasing hormone	Yes				Yes	Sandoz Teva Sun Pharma	8/4/1998 10/25/2000 3/9/2009	AP AP AP	3.3 5.6 13.9
<a href="#">Liraglutide</a>	<a href="#">Victoza</a>	1/25/2010	NCE	1/25/2015	expression of recombinant DNA in <i>Saccharomyces cerevisiae</i>									
<a href="#">Liraglutide</a>	<a href="#">Saxenda</a>	12/23/2014	new indication		expression of recombinant DNA in <i>Saccharomyces cerevisiae</i>									
<a href="#">Lucinactant</a>	<a href="#">Surfaxin</a>	3/6/2012	NCE	3/6/2012	synthetic formulation consisting of phospholipids, a fatty acid, and sinapultide (KL4 peptide), a 21-amino acid hydrophobic synthetic peptide									
<a href="#">Lutropin alfa</a>	<a href="#">Luveris</a>	10/8/2004	new dosage form	10/8/2009	recombinant human luteinizing hormone									
<a href="#">Mecasermin</a>	<a href="#">Increlex</a>	8/30/2005	NCE	8/30/2010	recombinant DNA of human insulin-like growth factor 1 (rhIGF-1)									
<a href="#">Nesiritide</a>		8/10/2001	NCE	8/10/2006	purified preparation of human B-type natriuretic peptide (hBNP), and is manufactured from <i>E. coli</i>									
<a href="#">Oxytocin</a>	<a href="#">Oxytocin</a>	7/9/1980	new formulation		Synthetic oxytocin					yes	Hikma Pharm Sagent	2/13/2013 10/29/2014	AP AP	32.6 34.3
<a href="#">Pegaplanib</a>	<a href="#">Macugan</a>	12/17/2004	NCE	12/17/2009	covalent conjugate of an oligonucleotide, to which two polyethylene glycol (PEG) units are covalently attached									
<a href="#">Pegvisomant</a>	<a href="#">Somavert</a>	3/25/2003	NCE	3/25/2008	recombinant DNA origin or <i>E. Coli</i>									
<a href="#">Pramlintide</a>	<a href="#">Symlin</a>	3/16/2005	NCE	3/16/2010	Synthetic analog of human amylin (neuroendocrine hormone)									
<a href="#">Secretin</a>	<a href="#">Chirhistim</a>	4/9/2004	NCE	4/9/2009	Synthetic human secretin peptide									
<a href="#">Albumin Human</a>	<a href="#">Optison</a>	12/31/1997	new dosage form		plasma of US donors									
<a href="#">Teduglutide</a>	<a href="#">Gattex</a>	12/21/2012	NCE	12/21/2016	Recombinant <i>E. Coli</i>									
<a href="#">Teriparatide</a>	<a href="#">Forteo</a>	11/26/2002	new dosage form		Recombinant <i>E. Coli</i>									
<a href="#">Tesamorelin</a>	<a href="#">Egrifla</a>	11/10/2010	NCE	11/10/2015	Synthetic peptide precursors of tesamorelin acetate (acetate salt) - analogue of human GRF									
<a href="#">Thyrotropin Alfa</a>	<a href="#">Thyrogen</a>	11/30/1998	NCE	11/30/2003	genetically modified Chinese hamster ovary cell line.									
<a href="#">Urofollitropin</a>	<a href="#">Bravelle</a>	5/6/2002	new dosage form		hormone purified from urine of postmenopausal women - peptide									
<a href="#">Enoxaparin</a>	<a href="#">Lovenox</a>	3/29/1993	NCE	3/29/1998	alkaline depolymerization of heparin benzyl ester derived from porcine intestinal mucosa	12/7/2006	13.7			Yes	Sandoz Amphastar	7/23/2010 9/19/2011	AP AP	17.3 18.5

Source: FDA.gov

Figure 3: 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
<b>Total</b>								<b>82,120</b>	<b>330,415</b>	<b>562,170</b>	<b>717,447</b>	<b>881,759</b>
Income Statement	2013A	1Q14A	2Q14A	3Q14A	4Q14E	2014E	2015E	2016E	2017E	2018E	2019E	2020E
<b>Total Revenue</b>	-	-	-	-	-	-	-	82,120	264,315	457,747	594,210	738,375
COGS	-	-	-	-	-	-	-	16,424	52,863	91,549	118,842	147,675
<b>Gross Profit</b>	-	-	-	-	-	-	-	65,696	211,452	366,198	475,368	590,700
<b>Operating Expenses</b>												
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
<b>Total Operating Expense</b>	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												
<b>Operating income</b>	(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)									
<b>Pre-tax income (GAAP)</b>	(60,690)	(19,457)	(16,640)	(17,431)	(18,404)	(71,932)	(95,032)	(54,048)	62,386	195,177	250,107	304,040
<b>Pre-tax income (non-GAAP)</b>												
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%
<b>Net Income (GAAP)</b>	(60,690)	(19,457)	(16,640)	(17,431)	(18,404)	(71,932)	(95,032)	(54,048)	39,303	122,961	157,568	191,545
<b>GAAP EPS (diluted)</b>	<b>(\$3.97)</b>	<b>(\$50.45)</b>	<b>(\$2.22)</b>	<b>(\$0.59)</b>	<b>(\$0.79)</b>	<b>(\$54.05)</b>	<b>(\$3.06)</b>	<b>(\$1.52)</b>	<b>\$1.05</b>	<b>\$3.14</b>	<b>\$3.83</b>	<b>\$4.43</b>
Diluted shares outstanding	15,278	388	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 4: RDUS valuation

Product	Peak Sales (\$MM)	Year	NPV at launch	Estimated launch	Time to launch	Probability Adjustment	Current Value (\$MM)	Scenario probability	Value / Share (NPV)	Value / Share (EV/Sales)
abaloparatide										
US	\$822	2022	\$1,364	6/1/2016	1.3	85%	\$955	100%	\$33	\$47
Ex-US - co-promote	\$346	2021	\$429	1/1/2017	1.9	85%	\$268	50%	\$5	\$11
Ex-US - royalty	\$346	2021	\$201	1/1/2017	1.9	85%	\$138	50%	\$2	\$11
Total abaloparatide							\$1,224		\$40	\$69
RAD-1901										
US	\$467	2023	\$670			35%	\$234		\$8	\$10
Ex-US	\$427	2023	\$188			35%	\$66		\$0	\$9
Total RAD-1901							\$300		\$8	\$19
Total Product Value							\$1,224		\$48	\$87
Cash							70		\$2	\$2
Total Equity Value							1,294		\$50	\$90
Shares Outstanding (MM)							29			
									Average	\$70

Risk-Free Rate	3.0%
Beta	1.8
Risk Premium	5%
Discount Rate	12%
EV/Sales	4.25

Insert figure here

Source: Canaccord Genuity Estimates

## Appendix: Important Disclosures

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### Target Price / Valuation Methodology:

Radius Health - RDUS

Our \$70 price target is based on the average of our probability adjusted NPV and EV/S methodologies.

### Risks to achieving Target Price / Valuation:

Radius Health - RDUS

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 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 than 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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Rating	Coverage Universe		IB Clients
	#	%	%
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Hold	332	32.45%	14.76%
Sell	45	4.40%	2.22%
Speculative Buy	51	4.99%	58.82%
	1023*	100.0%	

\*Total includes stocks that are Under Review



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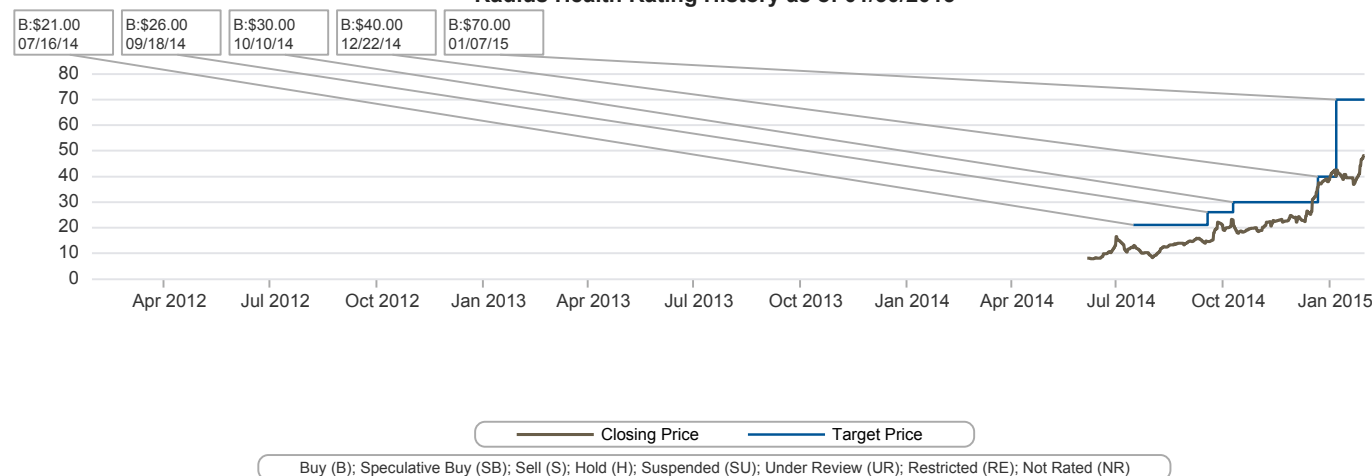
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