Radius Health (RDUS)

In-line 1Q Net Loss; Abaloparatide-SC Regulatory Filings on Track for 2H15

BUY
Price target $56.00
Price $36.04

EQUITY RESEARCH AMERICAS

Key Takeaway

With 24-month data including 6-mo ACTIVExtend extension study by end-2Q15, RDUS is on track for regulatory filings of abaloparatide-SC in osteoporosis in 2H15. For second product RDA1901 in ER+ mBC, initial update on Ph1 U.S. trial design & enrollment is expected at ASCO 2015, but unlikely efficacy data. Ph1 RAD1901 trial in EU is to begin in 2015.

In-line 1Q15 net loss of $17.1M (vs. ours of ~$17.5M). There was no revenue; OpEx of ~$16.3M was ~in line (vs. ours of $16.7M), including R&D of ~$11.6M (vs. ours of $11M) & G&A of $4.8M (vs. ours of $5.7M). We estimate RDUS' cash at end-1Q15 of ~$234M, including net proceeds of ~$158M from an equity raise on 1/15, should be sufficient thru 2016 without additional capital infusion (vs. into 4Q16 per RDUS).

On track for abaloparatide-SC NDA/MMA submission in 2H15 with 24-mo data expected by end-2Q15. The company has begun recruiting medical science liaisons (MSLs) in anticipation of a sales force build-out in 2016.

Likely no RAD1901 Ph1 efficacy data at ASCO 2015 given "trials in progress" designation; we await "add'l data" expected later this year. Mgmt continues to see RAD1901 well-positioned against competitors Faslodex from AstraZeneca (AZN, Buy), ARN-810 & potentially follow-on ARN-927/RG6047 from Roche (ROG VX, Buy) given RAD1901's: (1) tissue selectivity profile, (2) potential positive & protective effects on bone, and (3) potential to combine RAD1901 with other therapies, the latter of which RDUS believes is a crucial point of differentiation. An EU Ph1 trial focusing on PK in mBC patients is expected to begin in 2015.

Upcoming clinical events include: (1) optimization data on abaloparatide-TD at Transdermal Drug Delivery Systems Conference 5/11/15 in Philadelphia; initiation of clinical evaluation of optimized dose in 2H15; (2) Ph1 RAD1901 trial design/enrollment update at ASCO 2015; (3) Ph3 abaloparatide-SC 24-mo data (incl. 6-mo ACTIVExtend top-line fracture data) at end-2Q15 and responder analysis at EULAR in Rome 6/10/15-6/13/15; (4) abaloparatide-SC NDA and MAA submission in 2H15; (5) Ph2b trial initiation for low-dose RAD1901 as a SERM for vasomotor symptoms in 2H15; and (6) Ph1 trial initiation for RAD1901 in the EU in 2015.

Valuation/Risks

Our $56 PT is based on an NPV analysis of abaloparatide-SC & RAD1901. Risks include: (1) regulatory delays/failure & slow commercial uptake and/or competition of abaloparatide-SC & (2) development delay/failure of RAD1901.

USD	*Prev.*	2014A	*Prev.*	2015E	*Prev.*	2016E	*Prev.*	2017E
Rev. (MM)	--	0.0	--	0.0	--	90.0	--	99.8
EPS								
Mar	--	(50.45)	*(0.50)*	(0.47)A	--	--	--	--
Jun	--	(2.22)	*(0.45)*	(0.47)	--	--	--	--
Sep	--	(0.59)	*(0.44)*	(0.45)	--	--	--	--
Dec	--	(0.55)	*(0.43)*	(0.46)	--	--	--	--
FY Dec	--	(4.04)	*(1.82)*	(1.85)	*(0.40)*	(0.42)	*(1.09)*	(1.13)

EPS: RDUS completed its IPO in 2Q14

Financial Summary	
Book Value (MM):	$206.9
Book Value/Share:	$5.70
Net Debt (MM):	($234.2)
Long-Term Debt (MM):	$0.0
Cash/Share:	$6.45
Cash (MM):	$234.2

Market Data	
52 Week Range:	$51.22 - $7.46
Total Entprs. Value (MM):	$1,074.1
Market Cap. (MM):	$1,308.3
Shares Out. (MM):	36.3
Float (MM):	21.3
Avg. Daily Vol.:	419,932

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Price Performance

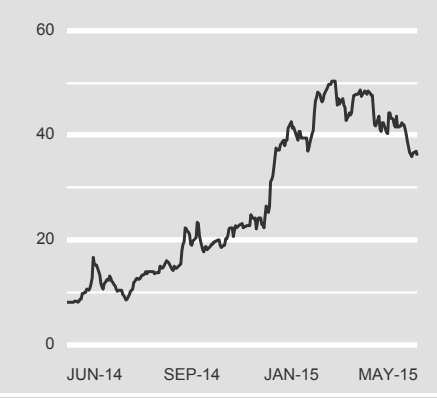

Chart 1: Radius Health's Product Pipeline

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	NDA/MAA filing in 2H15 (including 24 mo fracture data) & U.S./EU approval in 2016/2017, respectively; positive top-line Ph3 (18-mo) data reprted in 12/14; full data from ACTIVE + ACTIVExtend (24 mo) in 2Q15; ACTIVE 3 responder analysis at EULAR in Rome 6/10/15-6/13/15 Ph3 randomized (1:1:1) ACTIVE study (begun in 4/11, enrollment complete 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; 4/28/15 presented data from a post-hoc analysis (not prespecified in study protocol) relating to effects on bone mineral density/fracture risk at wrist showed abaloparatide showed 72% reduction in wrist fractures vs. teriparatide at ECTS-IBMS 2015; clinical significance will be evaluated during regulatory review of all ACTIVE data; ACTIVE trial demonstrated 86% reduction in vertebral fracture risk vs. placebo 6-month ACTIVExtend 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; on track to report data from ACTIVE + ACTIVExtend in 2Q15	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	5/11/15 presenting optimization data for TD patch at Transdermal Drug Delivery Systems Conference in Philly Clinical evaluation of optimized transdermal patch to begin in 2H15; 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; 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)	Ph1b open-label study in ER-positive mBC (U.S. trial) began in 12/14 in pts with ER-positive HER2-negative mBC (n=38) to determine safety, tolerability, and anti-tumor effects, with an update on trial design and enrollment progress at ASCO 2015 and further progress in 2H15; Ph1 trial in EU to begin in 2015; first part of two-part Phase 1 study in healthy subjects to determine MTD began in 2Q14 with data presented at San Antonio Breast Cancer Symposium, 12/9-12/13/14 Ph2b to define minimal effective dose (including 10mg and lower daily doses) in vasomotor symptoms to begin in 2H15	Radius	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

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Radius Health (RDUS)

Income Statement

($ in thousands except per share)

	2013	1Q14	2Q14	3Q14	4Q14	2014	1Q15	2Q15E	3Q15E	4Q15E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Revenues																					
Abaloparatide-SC for PMO (U.S.)												-	54,792	155,310	230,357	305,699	335,748	350,974	366,890	383,529	400,922
Growth y/y														*183%*	*48%*	*33%*	*10%*	*5%*	*5%*	*5%*	*5%*
Growth q/q																					
Royalty for abaloparatide-SC for PMO (EU)													-	9,074	25,210	36,651	47,676	51,325	52,590	53,886	55,215
Growth y/y															*178%*	*45%*	*30%*	*8%*	*2%*	*2%*	*2%*
RAD1901 for ER+ mBC (U.S.)																65,650	174,473	305,621	440,138	533,169	586,824
Growth y/y																	*166%*	*75%*	*44%*	*21%*	*10%*
Royalty for RAD1901 for ER+ mBC (EU)																-	13,261	34,546	56,942	80,381	95,443
Growth y/y																		*161%*	*65%*	*41%*	*19%*
Other revenues												90,000	45,000			180,000					
Total Revenues	-	-	-	-	-	-	-	-	-	-	-	**90,000**	**99,792**	**164,383**	**255,567**	**588,000**	**571,157**	**742,466**	**916,561**	**1,050,965**	**1,138,404**
% growth y/y														*64.7%*	*55.5%*	*130.1%*	*-2.9%*	*30.0%*	*23.4%*	*14.7%*	*8.3%*
Expenses																					
Cost of Goods Sold		-	-	-	-	-	-	-	-	-	-	-	9,863	23,296	32,250	47,619	62,839	76,189	96,111	108,507	116,671
% gross margin (Including royalties to Ipsen & Eisai)													*82.0%*	*85.0%*	*86.0%*	*87.2%*	*87.7%*	*88.4%*	*88.1%*	*88.2%*	*88.2%*
R&D	60,536	9,717	10,618	13,817	11,567	45,719	11,559	10,500	10,000	9,088	41,147	47,319	55,363	66,436	73,080	78,926	85,240	92,059	99,424	107,378	115,968
% growth y/y	*10.1%*					*-24.5%*					*-10.0%*	*15.0%*	*17.0%*	*20.0%*	*10.0%*	*8.0%*	*8.0%*	*8.0%*	*8.0%*	*8.0%*	*8.0%*
% of total revenues														*40.4%*	*28.6%*	*13.4%*	*14.9%*	*12.4%*	*10.8%*	*10.2%*	*10.2%*
SG&A	6,829	2,139	3,070	2,836	5,629	13,674	4,756	5,800	5,900	6,927	23,383	44,427	64,419	70,861	88,576	101,862	112,049	121,013	130,694	141,149	152,441
% growth y/y	*-27.9%*					*100.2%*					*71.0%*	*90.0%*	*45.0%*	*10.0%*	*25.0%*	*15.0%*	*10.0%*	*8.0%*	*8.0%*	*8.0%*	*8.0%*
% of total revenues													*64.6%*	*43.1%*	*34.7%*	*17.3%*	*19.6%*	*16.3%*	*14.3%*	*13.4%*	*13.4%*
Restructuring cost																					
Total Expenses	67,365	11,856	13,688	16,653	17,196	59,393	16,315	16,300	15,900	16,015	64,530	91,746	129,645	160,593	193,906	228,407	260,128	289,261	326,229	357,034	385,080
Income (loss) from Operations (EBIT)	**(67,365)**	**(11,856)**	**(13,688)**	**(16,653)**	**(17,196)**	**(59,393)**	**(16,315)**	**(16,300)**	**(15,900)**	**(16,015)**	**(64,530)**	**(1,746)**	**(29,853)**	**3,790**	**61,662**	**359,593**	**311,029**	**453,205**	**590,332**	**693,931**	**753,324**
% growth y/y																*483.2%*	*-13.5%*	*45.7%*	*30.3%*	*17.5%*	*8.6%*
Operating margin															*24.1%*	*61.2%*	*54.5%*	*61.0%*	*64.4%*	*66.0%*	*66.2%*
Other Income (Expense), Net	6,675	(2,632)	1,079	(767)	(766)	(3,086)	(742)	(750)	(750)	(758)	(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)	(17,962)	(62,479)	(17,057)	(17,050)	(16,650)	(16,773)	(67,530)	(15,546)	(42,453)	(2,510)	62,162	360,593	313,029	456,205	594,332	698,931	759,324
Provision for Taxes	–					–					–	–	–	–	–	18,030	31,303	68,431	118,866	174,733	227,797
Tax Rate																*5.0%*	*10.0%*	*15.0%*	*20.0%*	*25.0%*	*30.0%*
Net Income (Loss)	**(60,690)**	**(14,488)**	**(12,609)**	**(17,420)**	**(17,962)**	**(62,479)**	**(17,057)**	**(17,050)**	**(16,650)**	**(16,773)**	**(67,530)**	**(15,546)**	**(42,453)**	**(2,510)**	**62,162**	**342,563**	**281,726**	**387,774**	**475,466**	**524,198**	**531,527**
Extinguishment of preferred stock																					
Accretion of preferred stock	(17,471)	(4,969)	(4,031)			(9,000)															
Earnings to preferred stockholders																					
Unrealized loss from marketable securities							62				**62**										
Net Income (Loss) to Common Stockholders	**(78,161)**	**(19,457)**	**(16,640)**	**(17,420)**	**(17,962)**	**(71,479)**	**(17,057)**	**(17,050)**	**(16,650)**	**(16,773)**	**(67,530)**	**(15,546)**	**(42,453)**	**(2,510)**	**62,162**	**342,563**	**281,726**	**387,774**	**475,466**	**524,198**	**531,527**
EPS (LPS) - Basic	**(203.91)**	**(50.45)**	**(2.22)**	**(0.59)**	**(0.55)**	**(4.04)**	**(0.47)**	**(0.47)**	**(0.45)**	**(0.46)**	**(1.85)**	**(0.42)**	**(1.13)**	**(0.07)**	1.62	8.85	7.21	9.82	11.93	13.02	13.07
EPS (LPS) - Diluted	(203.91)	(50.45)	(2.22)	(0.59)	(0.55)	(4.04)	(0.47)	(0.47)	(0.45)	(0.46)	(1.85)	(0.42)	(1.13)	(0.07)	**1.44**	**7.83**	**6.38**	**8.69**	**10.55**	**11.52**	**11.56**
% growth y/y (diluted)																*445.6%*	*-18.6%*	*36.3%*	*21.4%*	*9.2%*	*0.4%*
Shares - Basic	383	386	7,500	29,746	32,678	17,699	36,269	36,450	36,633	36,816	36,542	37,184	37,556	37,931	38,311	38,694	39,081	39,471	39,866	40,265	40,667
Shares - Diluted	383	386	7,500	29,746	32,678	17,699	36,269	36,450	36,633	36,816	36,542	37,184	37,556	37,931	43,311	43,744	44,181	44,623	45,069	45,520	45,975
Cash, Cash Equivalents & Investments	12,303	29,558	79,021	68,514	105,276	105,276	234,174	217,124	200,474	183,701	183,701	168,155	125,702	123,192	185,354	527,917	809,644	1,197,418	1,672,883	2,197,082	2,728,608

Source: Company reports and Jefferies

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Company Description

Radius Health, Inc. 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 readout for ongoing Phase 3 for osteoporosis released on 12/22/14 and potential NDA filing in 2H15. Additional pipeline products include a transdermal patch of abaloparatide, abaloparatide-TD; RAD1901, an oral selective estrogen receptor down-regulator/ degrader (SERD) for the treatment of breast cancer brain metastases and vasomotor symptoms; and RAD140, a nonsteroidal selective androgen receptor modulator. Radius was founded in 2003 and is headquartered in Cambridge, Massachusetts.

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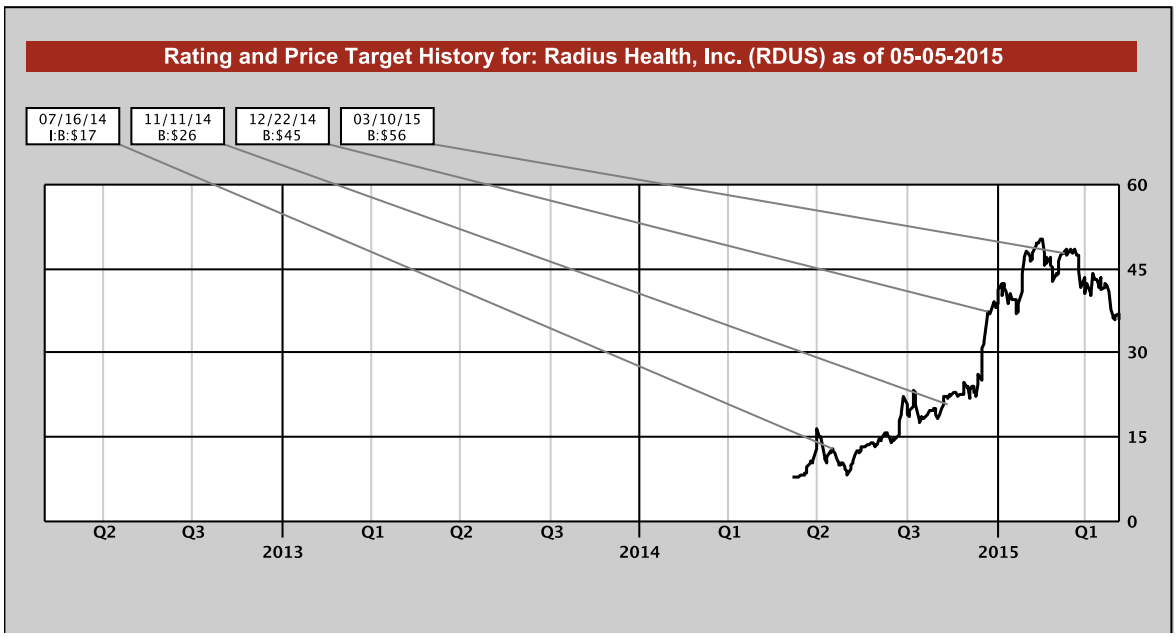
Other Companies Mentioned in This Report

- AstraZeneca PLC (AZN LN: p4,413.50, BUY)
- Roche (ROG VX: CHF262.50, BUY)
- Sagent Pharmaceuticals (SGNT: $23.68, HOLD)



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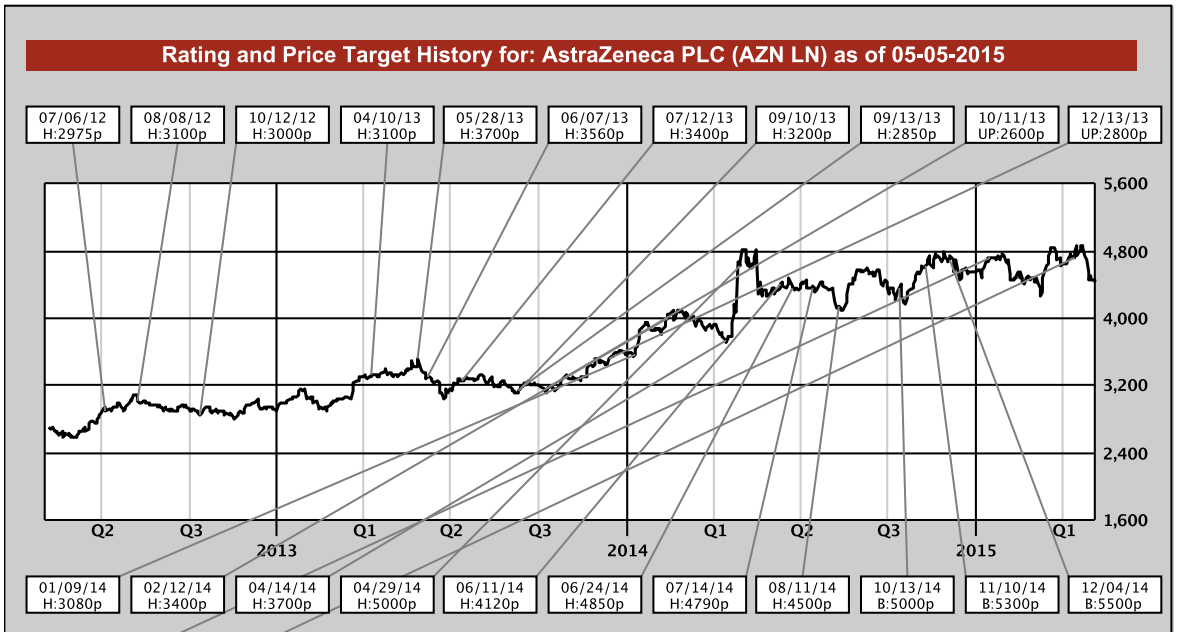

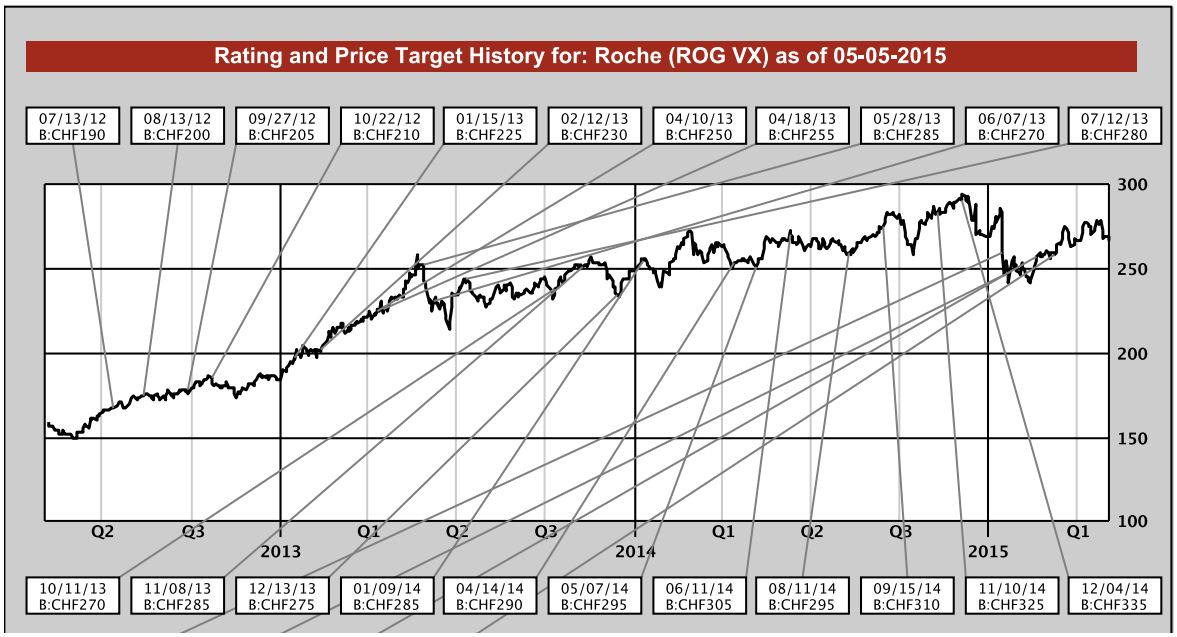

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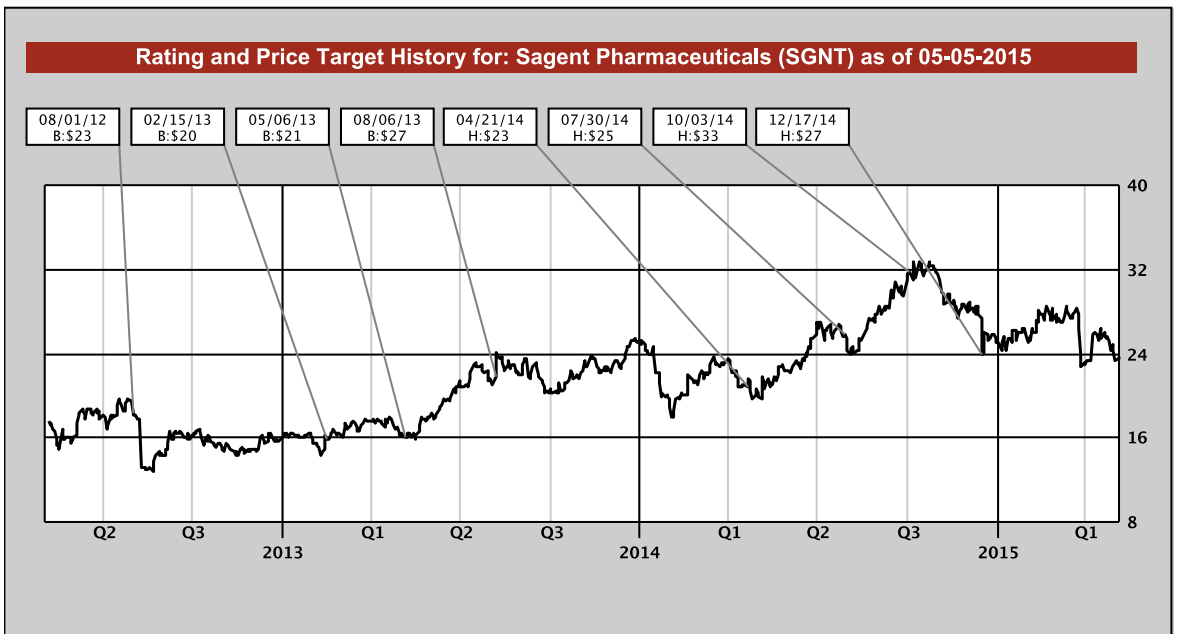

Distribution of Ratings

Rating	Count	Percent	IB Serv./Past 12 Mos. Count	IB Serv./Past 12 Mos. Percent
BUY	1064	51.23%	287	26.97%
HOLD	842	40.54%	160	19.00%
UNDERPERFORM	171	8.23%	11	6.43%

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