COMPANY NOTE

Target Change

USA | Healthcare | Biotechnology

February 13, 2015

Jefferies

Avalanche Biotechnologies (AAVL)

Expert Feedback Lends Additional Confidence in AVA-101

BUY

Price target $46.00
(from $40.00)
Price $36.28

EQUITY RESEARCH AMERICAS

Key Takeaway

We hosted an expert event with investors to assess the prospects of AVA-101 well in advance of PIIa data in mid-'15. Our expert believes AVA-101 could be the first gene therapy for macular degeneration and believes predictive animal eye models provide a high correlation to clinical activity. As a result, we maintain Buy rating and raise our PT to $46.

AVA-101 Data in Mid-15: AAVL's lead candidate is AVA-101, a gene therapy which may provide sustained anti-VEGF levels for wet AMD. The ongoing PIIa trial has enrolled 32 patients with baseline avg prior 13 injections, less extensive scarring (vs PI), and > 20/30 visual acuity at baseline. Our expert believes AAVL's subretinal injection delivery should be sufficient to produce adequate levels of sFLT-1 protein needed to inhibit VEGF, and for the PIIa believes the bar is low to advance into a PIIb trial. In his view, the bar is expected to be reduction in injection frequency and reductions in OCT outcomes. He believes a "win" could be if inj frequency in the active arm was 2 inj/pt/yr vs 8 inj/pt/yr. Regarding improvements in visual acuity, we tested him on letters gained and he believes these patients are refractory and therefore VA changes may be "all over the map" and would not be instructive on AVA-101's efficacy profile, and remains confident in this program given predictive data from preclinical trials. Another aspect of the trial to note is AVA-101's safety profile especially as it relates to vitrectomy but remains confident it will not cause any issues given data from AAVL PI data, and also data from PI/II trials w/ gene therapy trials involving rare retinal disease such as conducted by Spark Therapeutics (ONCE, $46.18, Not Covered) and Nightstarx (private).

Views On Other Retina Programs: Our expert clearly appears in the Regeneron (REGN, $401.74, Hold) camp regarding the Eylea/PDGF combo and believes the PI data provide support to move into PII, and thinks it differentiates vs Fovista on inj burden which could be a critical commercial issue. Regarding the upcoming Novartis (NOVN VX, 94.60, Buy) PII data on RTH-258 (vs Eylea), he thinks it will not differentiate to current anti-VEGF therapy. On Actavis' (ACT, $281.66) Abicipar (DARPin) it appears the intraocular inflammation should be resolved with PIII initiating later this year.

Valuation/Risks

We increase our PT to $46 on a slightly lower risk-adjusted discount to topline revenues. Risks include clinical, manufacturing, competitive, regulatory, and commercial.

Financial Summary	
Net Debt (MM):	($165.3)
Long-Term Debt (MM):	$0.0
Cash & ST Invest. (MM):	$165.3
Cash/Share:	$10.10
Cash (MM):	$165.3

Market Data	
52 Week Range:	$62.48 - $22.00
Total Entprs. Value (MM):	$429.7
Market Cap. (MM):	$595.0
Shares Out. (MM):	16.4
Float (MM):	17.7
Avg. Daily Vol.:	292,979

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USD	Prev.	2013A	Prev.	2014E	Prev.	2015E	Prev.	2016E
Rev. (MM)	--	0.5	--	0.4	--	2.0	--	0.0
EV/Rev		NM		NM		NM		
EPS								
Mar	--	--	--	(0.11)A	--	--	--	--
Jun	--	--	--	(2.27)A	--	--	--	--
Sep	--	--	--	(0.50)A	--	--	--	--
Dec	--	--	--	(0.33)	--	--	--	--
FY Dec	--	(1.45)	--	(3.55)	--	(0.87)	--	(0.94)
FY P/E		NM		NM		NM		NM

Price Performance

Valuation

We arrive at our $46 price target based on a DCF valuation model, which assumes a WACC of 14%, terminal growth rate of 0% and outstanding shares of 26.8 million, driven by sales of AVA-101. We assume market entry for AVA-101 for wet AMD in 2020 assuming positive data from a Phase III program. We estimate peak sales of $4.4 billion in the U.S. by 2026 for ophthalmic diseases including wet AMD, DME, and CRVO on an unadjusted basis. If we apply a 65% risk discount to reflect the clinical risk of the AVA-101 program, we estimate $1.5 billion in U.S. sales by 2026. Additionally, we expect $118 million in royalty revenue for the same indications in 2026 using a 65% risk-discount.

At this time, we do not model AVA-201 for wAMD or AVA-311 for juvenile X-linked retinoschisis (XLRS), and these products represent upside. We expect R&D expense to reach $16 million by YE 2014, increasing to $53 million by 2026 as AAVL ramps up clinical development of AVA-101 into DME and CRVO, AVA-201 and AVA-311. We expect SG&A expense to be $7.1 million by YE 2014, increasing to $46 million by 2026. We include $29 million in launch expenses for AVA-101 in 2021, risk-adjusted by 65%.

Exhibit 1: DCF sensitivity analysis

Equity Value	Price/Share
$1,760.2	$65.60
$1,466.8	$54.66
$1,230.1	**$45.84**
$1,038.0	$38.68
$881.6	$32.85

Source: Jefferies estimates

Risks

Clinical Failure: As with all companies in biotechnology and pharmaceuticals developing treatments of the future, a clinical failure can lead to delays in approval or possibly discontinuation of programs.

Regulatory Failure: The FDA could determine the Biologic Licensing Application is inadequate for AVA-101 for wet AMD and could delay approval. Furthermore, to date the FDA has not approved any gene therapy products for any indication. There is therefore no historical precedence for approval of such products, and the FDA may deem AAVL's clinical package for AVA-101 as insufficient for approval. Any delays in approval timelines could impact our earnings estimates, price target, and/or rating.

Commercial Failure: We currently estimate peak sales of $4.4 billion in the U.S. by 2026 for ophthalmic diseases including wet AMD, DME, and CRVO on an unadjusted-basis. If we apply a 65% risk discount to reflect the clinical risk of the AVA-101 program, we estimate $1.5 billion in U.S. sales by 2026. Additionally, we expect $117 million in royalty revenue for the same indications in 2026 using a 65% risk-discount. Our estimates may rely on the success of the company/partners to receive drug reimbursement from private/public payors.

Manufacturing Risks: AAVL relies on its proprietary baculovirus expression system (BVES) to produce its gene therapy products, including AVA-101. AAVL believes its BVES is efficient and scalable, with production yields up to 100x greater than those obtained by conventional AAV production system, allowing it to manufacture commercial grade

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production for large markets as wet AMD. If AVA-101 is approved, AAVL will need a consistent and reliable process, while limiting contamination risks, for manufacturing these candidates on a large scale for the approved patient population. Any supply or manufacturing disruption could negatively impact AVA-101 supply and sales.

Competitive Risks: Other companies are rapidly developing gene therapy product candidates in various stages of clinical development for ophthalmic diseases including wet AMD that may compete with AVA-101. If any of these product candidates have an improved therapeutic profile over AVA-101 and are approved, AVA-101's growth trajectory in the marketplace, even if approved, could be adversely impacted.

Financing Risks: We expect AAVL to have adequate cash through the majority of AVA-101's clinical development, and we model an $80 million equity raise on 2 million shares in 2019. AAVL may need additional dilutive financing to fund the potential U.S. launch of AVA-101 and its R&D programs in additional indications.

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Exhibit 2: AAVL Income Statement

Avalanche Biotechnologies, Inc.

Quarterly Income Statement

(All values in $MM except EPS and average shares)

	2012A	2013E	2014E					2015E					2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E	2026E
	FY	FY	1QA	2QA	3QA	4QE	FY	1QA	2QA	3QA	4QE	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY	FY
Revenue:																							
AVA101- U.S.	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	43.5	112.8	420.6	845.7	1317.5	1519.5	1538.0
AVA101- ROW royalty	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.2	49.3	94.2	112.1	121.3	118.0
License and collaboration revenues	0.0	0.5	0.0	0.1	0.2	0.0	0.4	0.5	0.5	0.5	0.5	2.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Total revenue, net	**0.0**	**0.5**	**0.0**	**0.1**	**0.2**	**0.0**	**0.4**	**0.5**	**0.5**	**0.5**	**0.5**	**2.0**	**0.0**	**0.0**	**0.0**	**0.0**	**43.5**	**123.0**	**469.9**	**939.9**	**1,429.7**	**1,640.8**	**1,656.0**
Costs and expenses:																							
Cost of goods sold	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	10.9	30.8	117.5	235.0	343.1	377.4	364.3
Research & development	13	2.2	0.9	3.1	5.7	6.3	16.1	4.5	4.5	4.5	4.5	18.0	18.0	40.0	42.0	44.1	45.9	47.2	48.7	49.6	50.6	51.6	52.7
Selling, general & administrative	0.5	18	0.7	15	2.4	2.5	7.1	18	18	18	19	7.3	7.4	7.6	7.7	7.9	8.0	37.2	39.1	41.0	42.7	44.4	45.7
Total operating expenses	**1.8**	**3.9**	**1.6**	**4.6**	**8.1**	**8.8**	**23.2**	**6.3**	**6.3**	**6.3**	**6.4**	**25.3**	**25.4**	**47.6**	**49.7**	**52.0**	**64.7**	**115.2**	**205.2**	**325.6**	**436.4**	**473.4**	**462.7**
Income (loss) from operations	**(1.8)**	**(3.5)**	**(1.6)**	**(4.5)**	**(7.9)**	**(8.8)**	**(22.8)**	**(5.8)**	**(5.8)**	**(5.8)**	**(5.9)**	**(23.3)**	**(25.4)**	**(47.6)**	**(49.7)**	**(52.0)**	**(21.3)**	**7.8**	**264.7**	**614.3**	**993.3**	**1,167.4**	**1,193.3**
Other income (expense):																							
Miscellaneous (expense) income	(0.0)	(19)	(0.0)	(3.9)	(0.3)	0.0	(4.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest income	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Interest expense	0.0	0.0	(0.0)	0.0	0.0	0.0	(0.0)	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net profit (loss) before income taxes	**(1.8)**	**(5.3)**	**(1.7)**	**(8.3)**	**(8.3)**	**(8.8)**	**(27.0)**	**(5.8)**	**(5.8)**	**(5.8)**	**(5.9)**	**(23.3)**	**(25.4)**	**(47.6)**	**(49.7)**	**(52.0)**	**(21.3)**	**7.8**	**264.7**	**614.3**	**993.3**	**1,167.4**	**1,193.3**
Income tax expense (benefit)														0.0	0.0	0.0	0.0	0.0	26.5	215.0	347.6	408.6	417.6
Income tax (%)														*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*10.0%*	*35.0%*	*35.0%*	*35.0%*	*35.0%*
Net Income (GAAP)	**(1.8)**	**(5.3)**	**(1.7)**	**(8.3)**	**(8.3)**	**(8.8)**	**(27.0)**	**(5.8)**	**(5.8)**	**(5.8)**	**(5.9)**	**(23.3)**	**(25.4)**	**(47.6)**	**(49.7)**	**(52.0)**	**(21.3)**	**7.8**	**15.0**	**399.3**	**645.6**	**758.8**	**775.6**
Adjusted Items (Non-GAAP)																							
Stock options	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.6	0.7	0.8	0.9	3.0	4.0	5.0	6.0	7.0	14.0	16.0	18.0	20.0	22.0	24.0	25.0
Depreciation and amortization expense	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Net Income (Non-GAAP)	**(1.8)**	**(5.3)**	**(1.7)**	**(8.3)**	**(8.3)**	**(8.8)**	**(27.0)**	**(5.2)**	**(5.1)**	**(5.0)**	**(5.0)**	**(20.3)**	**(21.4)**	**(42.6)**	**(43.7)**	**(45.0)**	**(7.3)**	**23.8**	**33.0**	**419.3**	**667.6**	**782.8**	**800.6**
EPS, GAAP																							
Basic	(0.50)	(1.45)	(0.45)	(2.27)	(0.50)	(0.33)	(3.55)	(0.22)	(0.22)	(0.22)	(0.22)	(0.87)	(0.94)	(1.74)	(1.80)	(1.74)	(0.70)	0.26	0.49	12.82	20.53	23.89	24.18
Diluted	**$ (0.50)**	**$ (1.45)**	**$ (0.45)**	**$ (2.27)**	**$ (0.50)**	**$ (0.33)**	**$ (3.55)**	**$ (0.22)**	**$ (0.22)**	**$ (0.22)**	**$ (0.22)**	**$ (0.87)**	**$ (0.94)**	**$ (1.74)**	**$ (1.80)**	**$ (1.74)**	**$ (0.70)**	**$ 0.26**	**$ 0.49**	**$ 12.82**	**$ 20.53**	**$ 23.89**	**$ 24.18**
Weighted average share- Basic	3.6	3.7	3.7	3.7	16.4	26.6	12.6	26.8	26.8	26.8	26.8	26.8	27.1	27.4	27.6	29.9	30.2	30.5	30.8	31.1	31.4	31.8	32.1
Weighted average share- Diluted	3.6	3.7	3.7	3.7	16.4	26.6	12.6	26.8	26.8	26.8	26.8	26.8	27.1	27.4	27.6	29.9	30.2	30.5	30.8	31.1	31.4	31.8	32.1

Source: Jefferies estimates, company data

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Exhibit 3: AAVL DCF analysis

Avalanche Biotechnologies

Discounted Cash Flow Analysis

(All values in $MM)	*2012A*	2013A	2014E	2015E	2016E	2017E	2018E	2019E	2020E	2021E	2022E	2023E	2024E	2025E
Sales	*0.0*	0.5	0.4	2.0	0.0	0.0	0.0	0.0	43.5	123.0	469.9	939.9	1,429.7	1,640.8
Operating Expenses	*1.8*	3.9	23.2	25.3	25.4	47.6	49.7	52.0	64.7	115.2	205.2	325.6	436.4	473.4
EBIT	*(1.8)*	(3.5)	(22.8)	(23.3)	(25.4)	(47.6)	(49.7)	(52.0)	(21.3)	7.8	264.7	614.3	993.3	1,167.4
(-): Taxes	*0.0*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	26.5	215.0	347.6	408.6
EBIAT	*(1.8)*	(3.5)	(22.8)	(23.3)	(25.4)	(47.6)	(49.7)	(52.0)	(21.3)	7.8	238.2	399.3	645.6	758.8
(+):Depreciation	*0.0*	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
(+):FAS-123 Options	*0.0*	0.0	0.0	3.0	4.0	5.0	6.0	7.0	14.0	16.0	18.0	20.0	22.0	24.0
(-): Capital expenditures	*0.0*	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.1	0.0	0.0
Unlevered free cash flow	***(1.8)***	***(3.5)***	***(22.9)***	***(20.3)***	***(21.5)***	***(42.6)***	***(43.8)***	***(45.0)***	***(7.3)***	***23.8***	***256.2***	***419.2***	***667.6***	***782.8***

Source: Jefferies estimates, company data

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Company Description

Avalanche Biotechnologies, Inc., a clinical-stage biotechnology company, focuses on discovering and developing novel gene therapies for the treatment of ophthalmic diseases based on its Ocular BioFactory platform. Its lead product candidate includes AVA-101, which is in a Phase I/IIa trial for the treatment of wet age-related macular degeneration (AMD). The company is also developing AVA-201, an anti-vascular endothelial growth factor gene therapy product candidate for the prevention of wet AMD; and AVA-311 that is in preclinical studies for the treatment of juvenile X-linked retinoschisis, a rare genetic disease of the retina with no approved therapy. Avalanche Biotechnologies, Inc. has a collaboration agreement with Regeneron Pharmaceuticals, Inc. research, develop, and commercialize gene therapy products. The company was founded in 2006 and is headquartered in Menlo Park, California.

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Valuation Methodology

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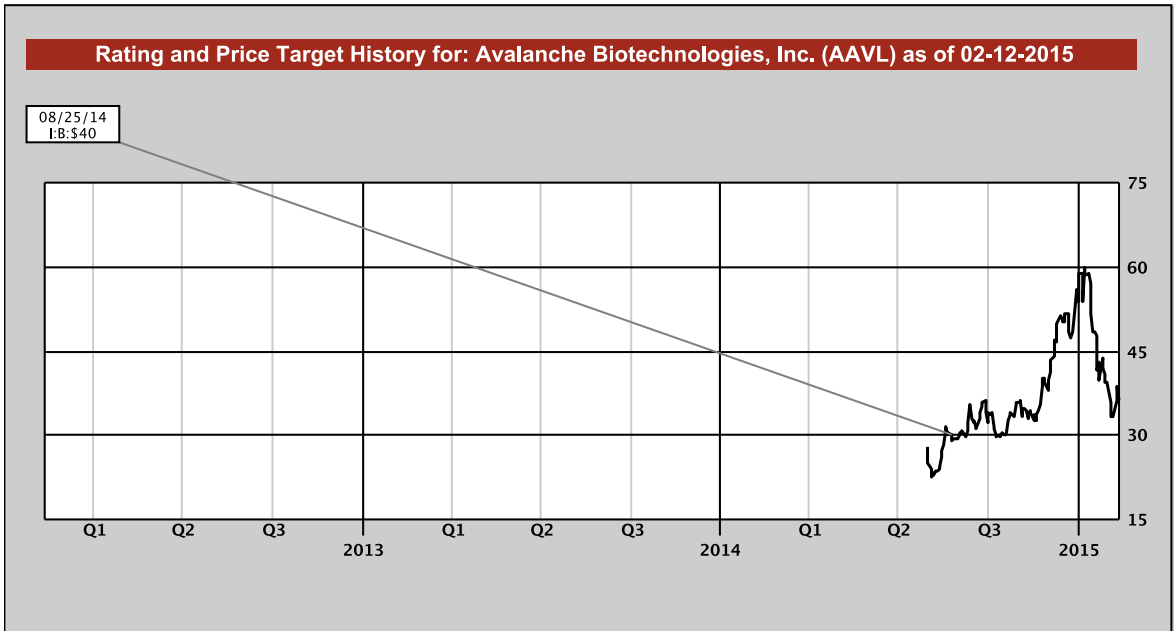
Other Companies Mentioned in This Report

- Actavis (ACT: $281.66, Suspended)
- Avalanche Biotechnologies, Inc. (AAVL: $36.28, BUY)
- Novartis AG (NOVN VX: CHF94.60, BUY)
- Regeneron Pharmaceuticals, Inc. (REGN: $401.74, HOLD)



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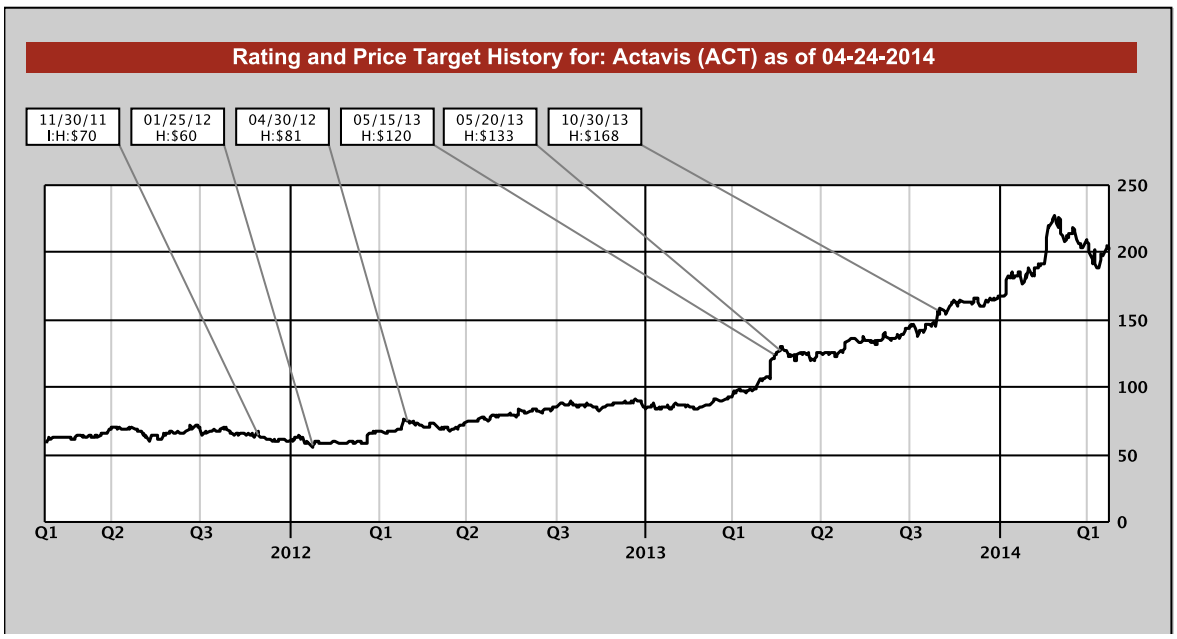

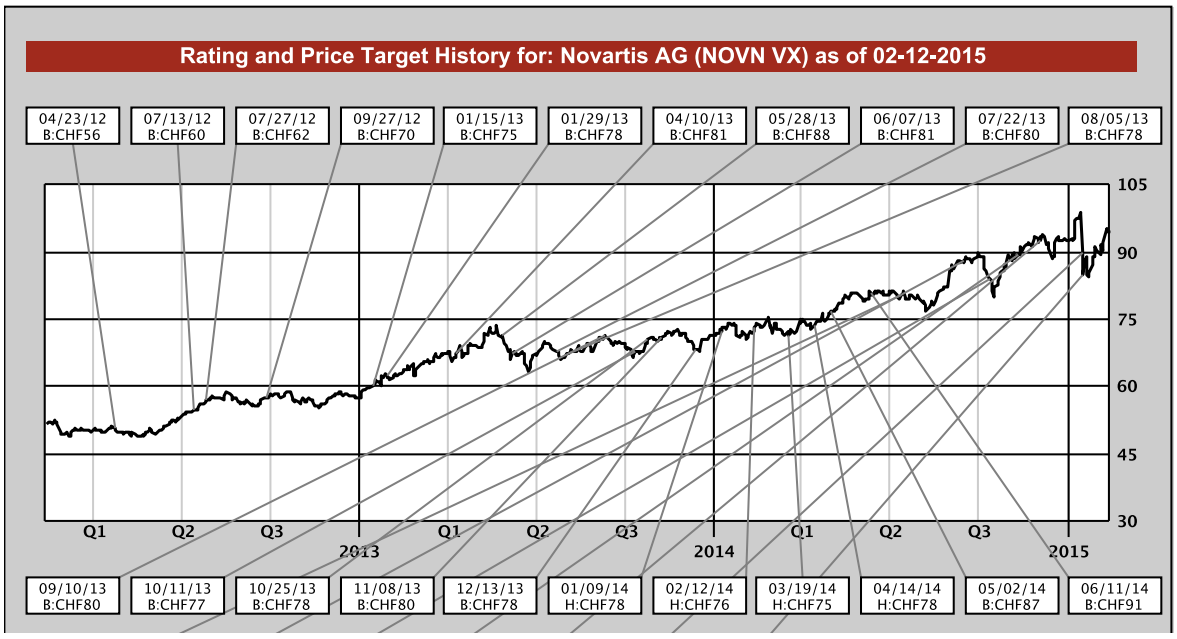

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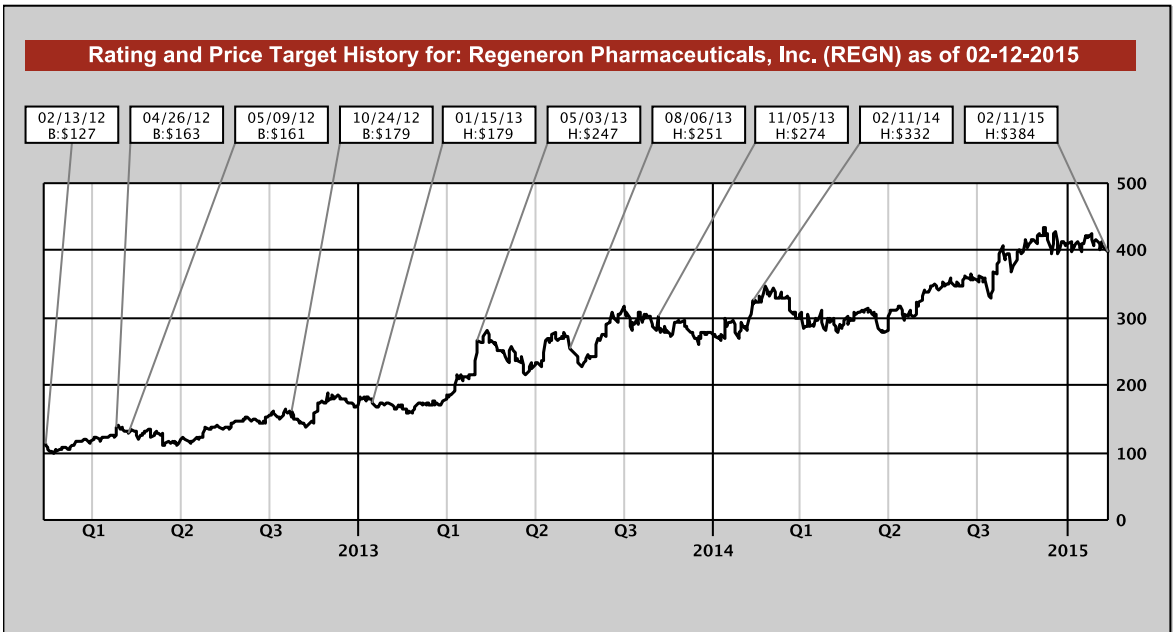

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Rating	Count	Percent	IB Serv./Past 12 Mos. Count	IB Serv./Past 12 Mos. Percent
BUY	1062	51.21%	289	27.21%
HOLD	838	40.41%	158	18.85%
UNDERPERFORM	174	8.39%	10	5.75%

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