Versartis

VSAR : NASDAQ : US$29.98

BUY

Target: US$45.00

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COMPANY STATISTICS:

Market Cap (M):	US$698.5
52-week Range:	23.51 - 36.30
Avg. Daily Vol. (000s):	121.8

EARNINGS SUMMARY:

FYE Dec		2013A	2014E	2015E
Revenue (M):		0.0	0.0	0.0
EPS:		(1.99)	(3.00)	(2.34)
Revenue (M):	Q1	0.0	0.0A	0.0
	Q2	0.0	0.0	0.0
	Q3	0.0	0.0	0.0
	Q4	0.0	0.0	0.0
Total		0.0	0.0	0.0
EPS:	Q1	-	(16.13)A	(0.49)
	Q2	-	(0.52)	(0.55)
	Q3	-	(0.60)	(0.64)
	Q4	-	(0.43)	(0.68)
Total		(1.99)	(3.00)	(2.34)

SHARE PRICE PERFORMANCE:

Source: Interactive Data Corporation

COMPANY DESCRIPTION:
Versartis is a development-stage biotechnology company focused on the development and commercialization of its primary drug candidate, VRS-317 for growth hormone treatment. Versartis aims to develop a drug given less frequently in order to decrease injection burden, potentially leading to increased compliance and better treatment outcomes.

All amounts in US$ unless otherwise noted.

Life Sciences -- Biotechnology

SIX-MONTH DATA POSITIVE, ALL DOSES VIABLE FOR PHASE 3

All doses viable for Phase 3

Six month data suggest all three doses for VRS-317 are viable for Phase 3, including monthly. As expected, annualized growth velocities were slightly lower at six months vs. three months. Importantly, the monthly dose showed a smaller decrease versus semi-monthly. Annualized growth rates at six months were: 5.0 mg/kg monthly: 7.9 cm/yr vs. 8.15 cm/yr at three months. 2.5 mg/kg semi-monthly: 8.7 cm/yr vs. 9.21 cm/yr at three months. 1.35 mg/kg weekly: 7.6 cm/yr vs. 7.8 cm.yr at three months.

Safety greatest asset, continues to be clean

Very importantly, safety for VRS-317 at six months was very clean, with the vast majority of AEs reported as mild. Specifically, no nodules or lipoatrophy were seen at injections sites. More than 80% of patients had two or fewer occurrences of injection site reactions. One investigator stated that simply changing the injection site completely resulted in zero injection site reactions in one of his patients. We believe that the safety profile for VRS-317 could support an even higher dose due to its very clean profile.

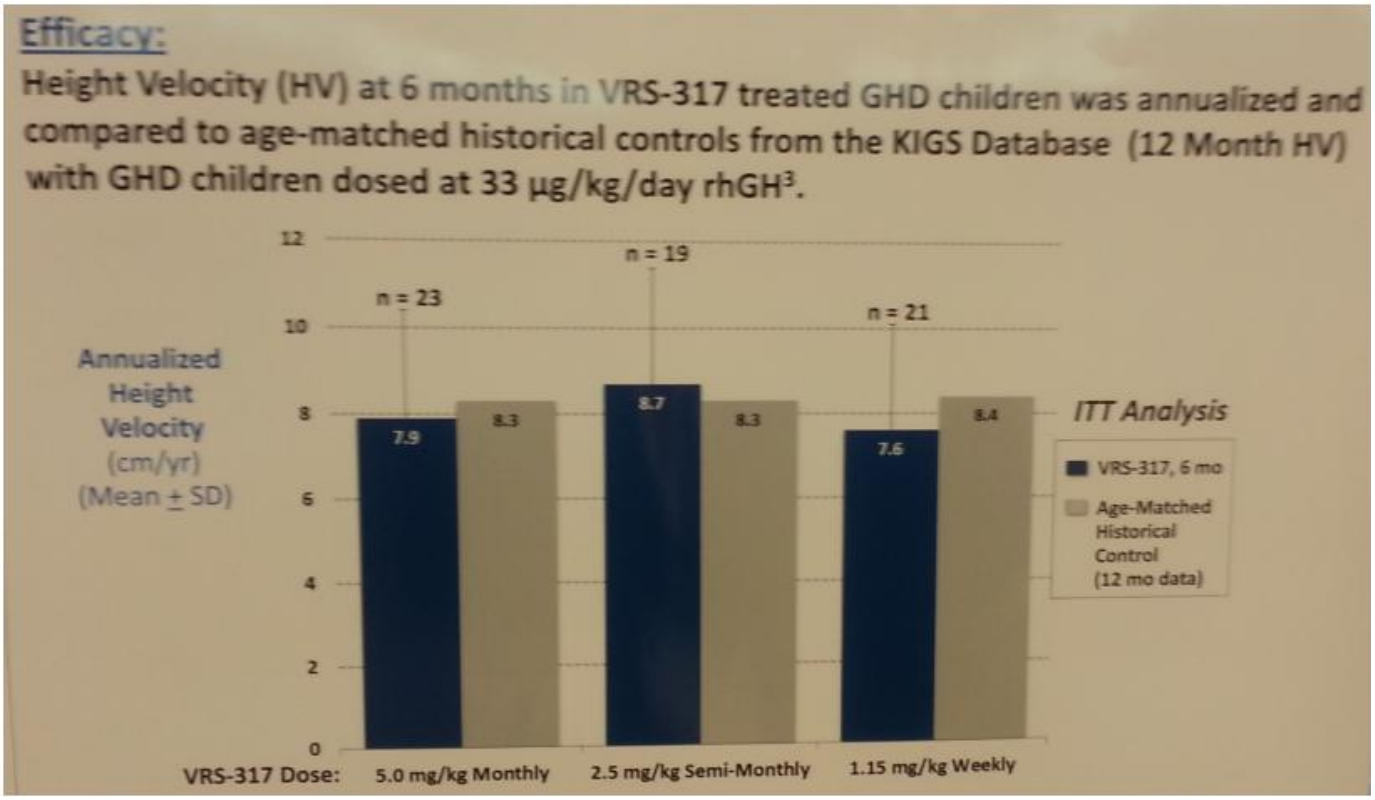
Await FDA meeting in August for Phase 3 details

Versartis will provide details of the Phase 3 design after meeting with FDA later this summer. We believe that the study design may involve two active dosing arms.

ALL DOSES VIABLE AT 6-MONTHS

We believe that all three doses of VRS-317 are viable at six months, supported by height velocity data consistent with three months. Importantly, the monthly dose annualized height velocity declined less than the semi-monthly dose. We believe that Versartis has dose flexibility in terms of moving multiple doses into Phase 3, and that the monthly dose remains viable.

Figure 1: VRS-317 annualized height velocity data at six months



Source: ENDO 2014, Versartis

Height velocity change lower for monthly vs. semi-monthly dose

Importantly, annualized height velocity for the 5.0 mg/kg dose at six months vs three months changed *less* than annualized height velocity for the semi-monthly dose. We believe that this supports the continued viability of the monthly dose, since the expected decline was lower than that of the semi-monthly dose. The monthly dose had a six-month annualized growth rate of 7.9 cm/yr vs. 8.15 cm/yr at three months, a decrease of .25 cm/yr. However, the semi-monthly dose showed a decline of 0.51 cm.yr for its six-month annualized growth rate vs. three months (8.7 cm/yr at six months vs. 9.21 cm/yr at three months). We believe the smaller change for the monthly dose is encouraging and suggests that efficacy is well maintained.

SAFETY REMAINS CLEAN AT ALL DOSES

There are no surprises on safety at six months, in our view, with most adverse events being Grade 1 mild. In terms of injection site reactions, one investigator remarked that a patient who had experienced a mild injection site reaction had no further reactions at the next visit when the injection site was rotated. There were n=6 transient IGF-1 levels above 2 SDS in the monthly dose group, but they quickly returned to baseline and never exceeded 3.0 SDS. We do not believe that transientIGF-1 levels above 2.0 are an issue in terms of safety.

Also, there was no accumulation of IGF-1 at any dose, which is very encouraging (Figure 3). We believe that the safety profile for VRS-317 could allow for even higher dosing if so desired by Versartis.

Figure 2: VRS-317 safety profile

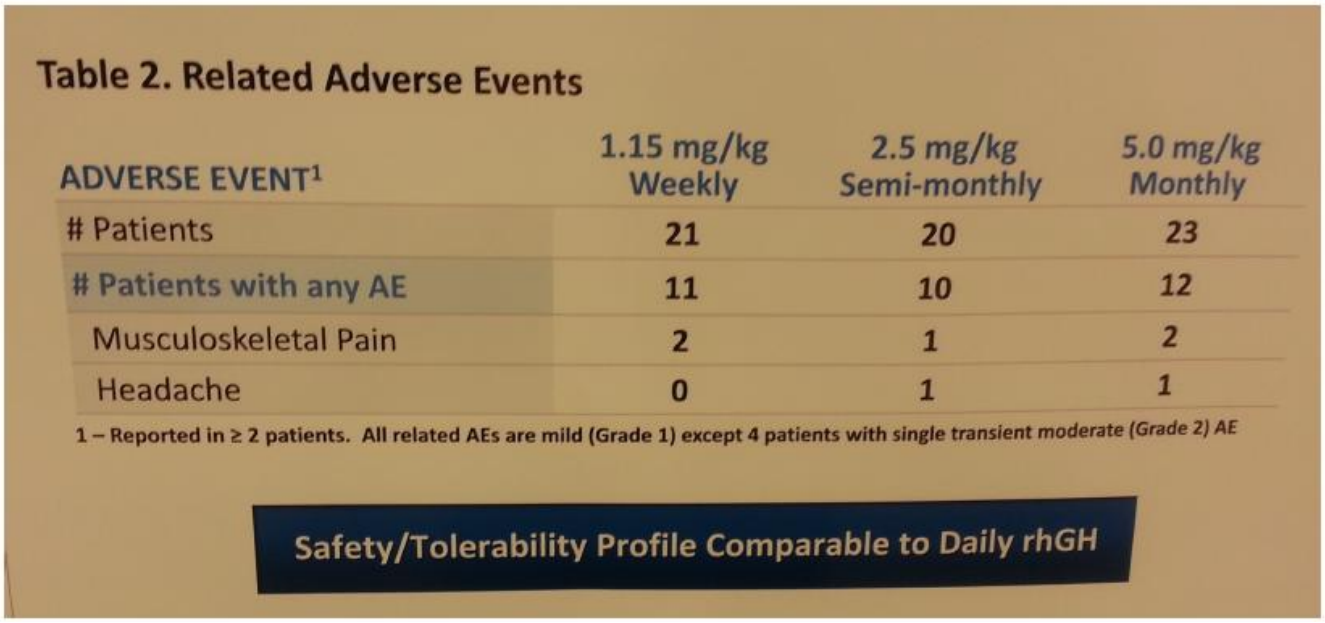


Table 2. Related Adverse Events

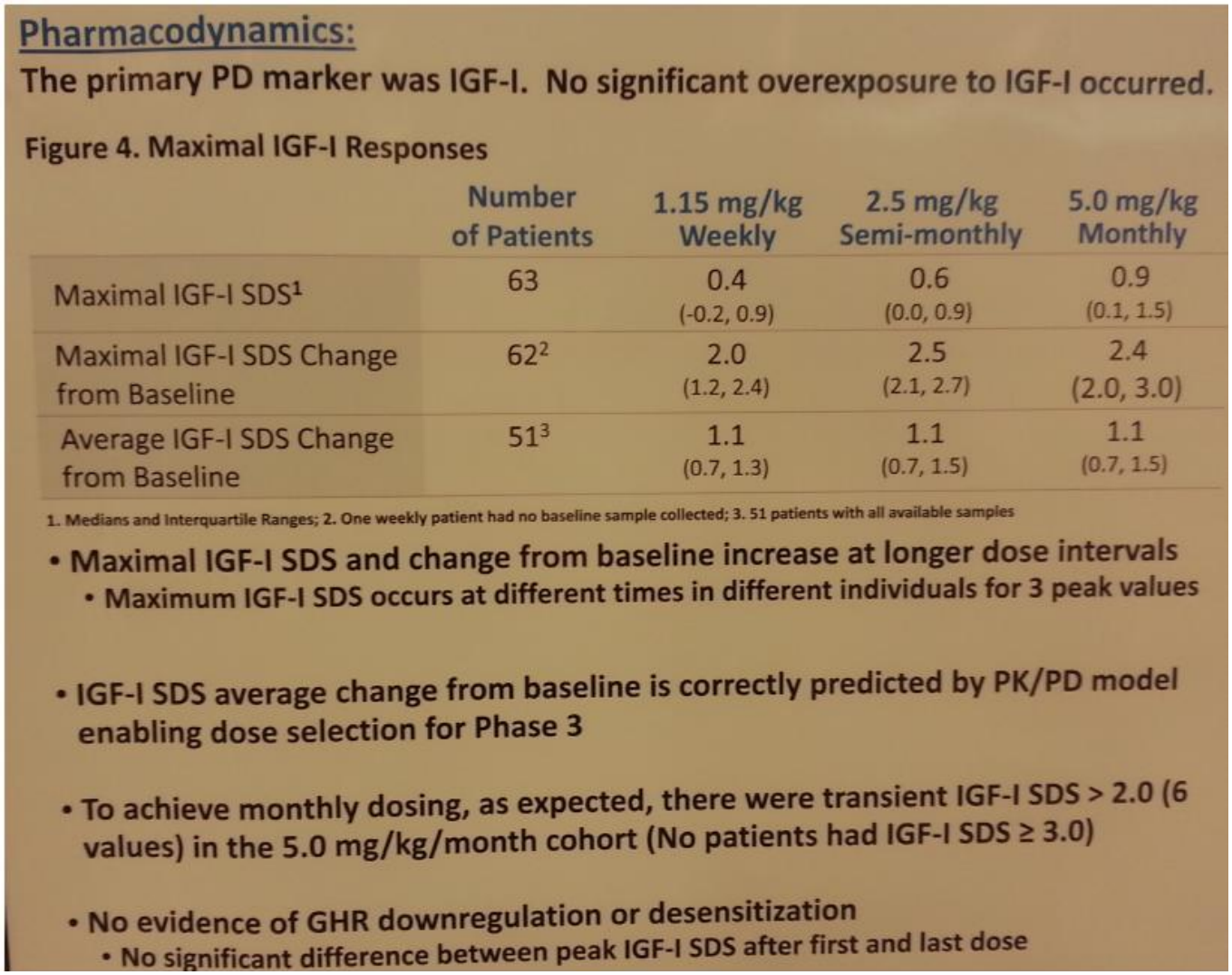
ADVERSE EVENT[1]	1.15 mg/kg Weekly	2.5 mg/kg Semi-monthly	5.0 mg/kg Monthly
# Patients	21	20	23
# Patients with any AE	11	10	12
Musculoskeletal Pain	2	1	2
Headache	0	1	1

1 – Reported in ≥ 2 patients. All related AEs are mild (Grade 1) except 4 patients with single transient moderate (Grade 2) AE

Safety/Tolerability Profile Comparable to Daily rhGH

Source: ENDO 2014, Versartis

Figure 3: VRS-317 IGF-1 levels



Pharmacodynamics:

The primary PD marker was IGF-I. No significant overexposure to IGF-I occurred.

Figure 4. Maximal IGF-I Responses

	Number of Patients	1.15 mg/kg Weekly	2.5 mg/kg Semi-monthly	5.0 mg/kg Monthly
Maximal IGF-I SDS[1]	63	0.4 (-0.2, 0.9)	0.6 (0.0, 0.9)	0.9 (0.1, 1.5)
Maximal IGF-I SDS Change from Baseline	62[2]	2.0 (1.2, 2.4)	2.5 (2.1, 2.7)	2.4 (2.0, 3.0)
Average IGF-I SDS Change from Baseline	51[3]	1.1 (0.7, 1.3)	1.1 (0.7, 1.5)	1.1 (0.7, 1.5)

1. Medians and Interquartile Ranges; 2. One weekly patient had no baseline sample collected; 3. 51 patients with all available samples

- Maximal IGF-I SDS and change from baseline increase at longer dose intervals
  - Maximum IGF-I SDS occurs at different times in different individuals for 3 peak values
- IGF-I SDS average change from baseline is correctly predicted by PK/PD model enabling dose selection for Phase 3
- To achieve monthly dosing, as expected, there were transient IGF-I SDS > 2.0 (6 values) in the 5.0 mg/kg/month cohort (No patients had IGF-I SDS ≥ 3.0)
- No evidence of GHR downregulation or desensitization
  - No significant difference between peak IGF-I SDS after first and last dose

Source: ENDO2014, Versartis

BASELINE VALUES LIKELY SIGNIFICANTLY DIFFERENT THAN PROLOR – VERSARTIS US PATIENTS MORE REPRESENTATIVE

As shown in Figure 4, patients in the Phase 2 VRS-317 study had baseline height SDS levels of ~ -2.5, typical of US patients. Also, baseline IGF-1 levels were ~ -1.72, also typical of US pediatric growth hormone deficient patients. Prolor's Phase 2 study is enrolling patients in Eastern Europe, where height SDS and IGF-1 SDSvalues tend to be much lower at baseline. Very low height SDS and IGF-1 SDS levels at baseline can result in high growth velocities, but patients still end up far below normal in terms of ending height SDS. Therefore, we would do not believe that Prolor's interim Phase 2 data are a good comparator to Versartis' VRS-317.

Figure 4: VRS-317 Phase 2 demographics

Table 1. Phase 2a Demographic Data (Mean ± SD)

	All Patients	1.15 mg/kg Weekly	2.5 mg/kg Semi-monthly	5.0 mg/kg Monthly
# Patients	64	21	20	23
Age (Screening)	7.83 (2.4)	7.51 (2.3)	7.96 (2.4)	8.01 (2.5)
Males/Females	37/27	10/11	13/7	14/9
Height SDS	-2.51 (0.5)	-2.70 (0.7)	-2.53 (0.4)	-2.33 (0.5)
Weight (kg)	20.8 (6.4)	19.1 (5.3)	21.8 (7.4)	21.4 (6.4)
Bone Age	6.4 (2.4)	6.1 (2.5)	6.6 (2.2)	6.4 (2.6)
GH Stimulation Test	5.4 (2.6)	5.7 (2.0)	4.9 (2.8)	5.5 (2.8)
IGF-I SDS	- 1.72 (0.8)	-1.55 (0.9)	-2.00 (0.8)	-1.62 (0.7)
Phase 1b	44/64	14/21	14/20	16/23
Phase 1b Mean Dose	2.9 (1.8)	2.7 (1.8)	2.9 (1.9)	3.0 (1.8)

- No clinically or statistically significant differences between groups
- Patients were enrolled in 25 clinical sites in the US only
- Age and height SDS are representative of US pediatric GHD patient population and are the primary and secondary determinants of growth

Source: ENDO2014, Versartis

Figure 5: VSAR valuation

Product	Peak Sales ($MM)	Peak Year	Current Value ($MM)	Probability Adjustment	Value / Share
US					
Pediatrics - GHD	$ 443	2027	$357	65%	$10
Adults - GHD	$ 108	2027	$92	65%	$2
Turner Syndrome	$ 83	2027	$69	65%	$2
ISS + Other	$ 464	2027	$389	65%	$10
Total	**$ 1,099**		**$907**		**$24**
EU - Co-Promote					
Pediatrics - GHD	$ 203	2027	$258	65%	$7
Adults - GHD	$ 60	2027	$74	65%	$2
Turner Syndrome	$ 37	2027	$46	65%	$1
Other	$ 80	2027	$99	65%	$3
Total	**$ 381**		**$478**		**$13**
Japan - Royalties					
Pediatrics - GHD	$ 60	2027	$79	65%	$2
Adults - GHD	$ 3	2027	$23	65%	$1
Other	$ 13	2027	$18	65%	$0
Total	**$ 75**		**$120**		**$3**
Net Cash					$100
Total Equity Value					$978
Shares Outstanding					24
Value Per Share					$45

Risk-Free	2.0%
Beta	1.5
Risk premium	8%
Total discount rate	14%
Effective Discount Rate	22%
Date	Jun-14

Source: Canaccord Genuity, LLC

Investment risks

Primary risks to our rating and price target include the following: VRS-317 may not produce positive Phase 2a data at its six-month readout for monthly, semi-monthly, or weekly dosing, even if positive data is produced Phase 3 data may not be positive and the FDA may not approve VRS-317 for any indication, future litigation may delay or reduce revenues, and increased competition may reduce revenues below our current estimates.

VRS-317 may not show positive Phase 2a data at its six-month readout in June 2014, and even if it does, weekly or semi-monthly dosing may prove to be a more viable treatment option. If dosing is reduced from a monthly treatment to semi-monthly or weekly, VRS-317's competitive advantage versus current and future competitors will be reduced. We see the strength of VRS-317 in its monthly dosing and do not believe patients and doctors will view a semi-monthly treatment option as a very meaningful difference from weekly dosing, should currently in development products be approved.

Litigation from Novo, Roche, or Pfizer may delay VRS-317's entry onto the market, assuming positive data and FDA approval. Depending on the extent of the delay, revenues may be greatly reduced and future cash flows diminished as we expect Versartis' VRS-317 patents will expire in 2030.

Future competition in the growth hormone market may increase, lowering estimated market share for VRS-317 and reducing revenues for Versartis. Should another long-acting growth hormone product be introduced, we expect revenues could be negatively impacted. Growth hormone treatment is a field dominated by several players and new entrants could result in strong competition.

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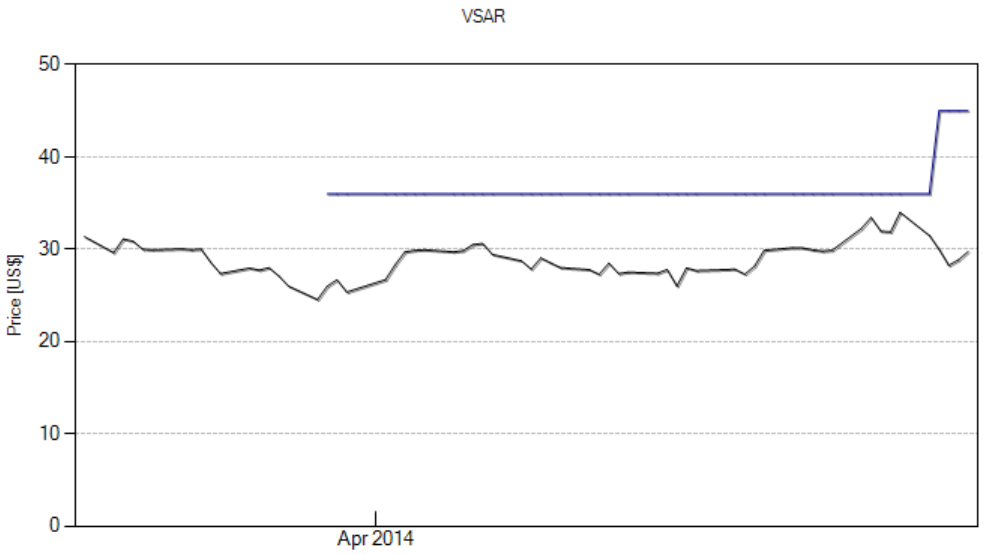
Site Visit: An analyst has not visited Versartis' material operations.

Price Chart:*



	Date	Analyst	Rating	Target Price		Date	Analyst	Rating	Target Price
1)	04/15/2014	Newman	Buy	36.00	2)	06/16/2014	Newman	Buy	45.00

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

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Global Stock Ratings
(as of 31 March 2014)

	Coverage Universe		IB Clients
Rating	#	%	%
Buy	580	58.7%	37.1%
Speculative Buy	43	4.4%	55.8%
Hold	317	32.1%	13.2%
Sell	45	4.6%	4.4%
	988*	100.0%	

*Total includes stocks that are Under Review

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