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Oramed Pharmaceuticals, Inc. (ORMP)

Earnings Update

Healthcare

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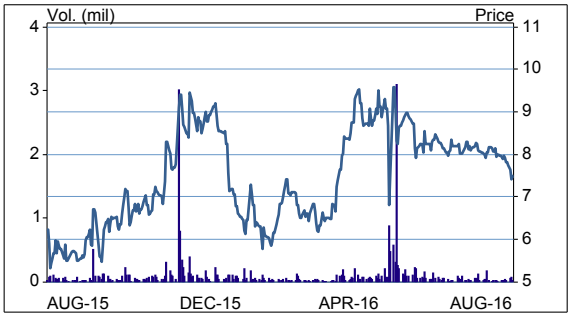
Looking Towards Next Round of Catalysts; Reiterate Buy

Stock Data	08/17/2016
Rating	Buy
Price	$7.49
Exchange	NASDAQ
Price Target	$25.00
52-Week High	$10.74
52-Week Low	$4.15
Enterprise Value (M)	$74
Market Cap (M)	$98
Public Market Float (M)	9.6
Shares Outstanding (M)	13.1
3 Month Avg Volume	114,570
Short Interest (M)	0.47
Balance Sheet Metrics	
Cash (M)	$34.00
Total Debt (M)	$0.00
Total Cash/Share	$1.88
Book Value/Share	$2.36

Cash (M): pro forma

EPS Diluted			
Full Year - Aug	2015A	2016E	2017E
1Q	(0.19)	(0.24)A	(0.12)
2Q	(0.16)	(0.14)A	(0.13)
3Q	(0.15)	(0.15)A	(0.17)
4Q	(0.18)	(0.14)	(0.19)
FY	(0.67)	(0.65)	(0.62)



Phase 2b trial data lays groundwork for pivotal program. We note that primary and secondary endpoint analyses of data from Oramed's Phase 2b trial of ORMD-0801 underscore the positive profile of Oramed's orally-bioavailable insulin lead candidate and could pave the way for an End-of-Phase 2 meeting with the FDA and finalization of the design of pivotal studies. In our view, As reported late last month, ORMD-0801 demonstrated favorable impact across a range of different glucose parameters as well as statistically significant impact on HbA1c, which was particularly encouraging given the relative short duration of the trial at only four weeks. In anticipation of Oramed's potential meeting with the FDA to finalize the design of the ORMD-0801 pivotal program, we reiterate our Buy rating and price target of $25.00 per share.

Solid financial base and low burn rate constitute positives. In our view, the fact that Oramed has now received over $25M from its Chinese partner on ORMD-0801, Hefei Tianhui Incubator of Technologies Co. Ltd. (HTIT), reflects solidly on the achievements that Oramed has attained to date with the ORMD-0801 program. In addition, HTIT's non-dilutive capital means that Oramed—which, according to our calculations, has roughly $34M in *pro forma* cash—likely has an operational runway extending for over two years.

Discounted technology platform. Oramed currently trades at an enterprise value well under $100M, while the global diabetes market may exceed $40B by 2018. In our view, the market continues to discount the value of the company's pipeline, particularly ORMD-0801, and we believe that the additional data from the firm's completed Phase 2b trial could spur interest from potential licensing partners for ex-China territories.

Valuation methodology, risks and uncertainties. Factoring in a 12% discount rate, a 60% probability of success for ORMD-0801, and peak annual sales of $2.1B (on which we project double-digit percentage royalties), we derive a total rNPV of $150M. We add to this the value from Oramed's pipeline, mainly ORMD-0901, to which we ascribe a valuation of $180M, to derive a total firm value of $365M. This translates into a price objective of $25.00 per share, assuming net cash of ~$35M and ~14M fully-diluted shares outstanding as of end-fiscal 2017. Risks to our target include, but are not limited to: (1) delays in the advancement of ORMD-0801 into pivotal testing; (2) adverse results from future clinical trials; and (3) negative regulatory actions.

Additional ORMD-0801 Phase 2b Clinical Trial Endpoint Data

In late July 2016, Oramed presented follow-up data from its previously-completed Phase 2b trial of ORMD-0801 in type 2 diabetic patients. The study was conducted in 188 subjects, 64 of whom received a placebo. A total of 124 patients were given ORMD-0801, 61 of whom received the drug at a 460IU (16mg) dose, and the remainder of whom received a 690IU (24mg) dose. The number of discontinuations during this 28-day trial was very low—two subjects in the placebo group (3.1%); four subjects in the ORMD-0801 low-dose group (6.6%); and two subjects in the ORMD-0801 high-dose group (3.2%). Overall, the discontinuation rate was 4.3% (eight subjects). In our view, a sub-5% discontinuation rate may be considered very favorable for a trial of this size.

The principal aim of this Phase 2b trial was to evaluate the pharmacodynamics effects of ORMD-0801 on mean night-time glucose, evaluated using continuous glucose monitoring (CGM). Evaluation of safety, including incidence of hyperglycemia, was also a central objective of the trial. Other secondary objectives included evaluation of change from baseline in fasting blood glucose (FBG), morning fasting serum insulin, c-peptide, and triglycerides. Exploratory objectives included the evaluation of ORMD-0801 immunogenicity through measurement of anti-insulin antibodies, along with the following assessments: change from baseline in HbA1c; 24-hour, fasting and daytime glucose levels determined using CGM; changes in body weight; and changes in C-reactive protein (CRP).

ORMD-0801 Phase 2b Trial Patient Demographics

The table below outlines the demographic characteristics of patients enrolled into Oramed's Phase 2b trial of ORMD-0801. As can be observed below, the populations in each arm of the study demonstrated comparable characteristics and therefore no errors in randomization were determined to have occurred in this study.

Table 1: Phase 2b Trial Demographic Summary

	Placebo (N=64)	ORMD-0801 460IU (N=61)	ORMD-0801 690IU (N=63)
Sex - n (%)			
Male	29 (45.3)	39 (63.9)	34 (54.0)
Female	35 (54.7)	22 (36.1)	29 (46.0)
Race - n (%)			
White	53 (82.8)	50 (82.0)	55 (87.3)
Black or African American	7 (10.9)	8 (13.1)	4 (6.3)
Asian	2 (3.1)	2 (3.3)	2 (3.2)
American Indian or Alaskan Native	0	0	0
Native Hawaiian or Other Pacific Islander	2 (3.1)	1 (1.6)	0
Other	0	0	2 (3.2)
Ethnicity - n (%)			
Hispanic or Latino	31 (48.4)	32 (52.5)	36 (57.1)
Not Hispanic or Latino	33 (51.6)	29 (47.5)	27 (42.9)
Not Reported	0	0	0
Age (years)			
Sample Size	64	61	63
Mean	58.61	57.89	57.25
Standard Deviation	9.203	8.021	8.786
Median	58.80	58.45	58.07
Min, Max	37.3, 75.9	36.5, 75.7	31.0, 71.0
Coefficient of Variation	15.701	13.855	15.347

Source: Oramed Pharmaceuticals, Inc.

We note, firstly, that the trial met its central safety objective, as ORMD-0801 was generally safe and well-tolerated with no instances of severe hyperglycemia or hypoglycemia. The safety profile of ORMD-0801 was thus confirmed based on what had previously been observed in prior trials of this candidate.

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Data Trimming

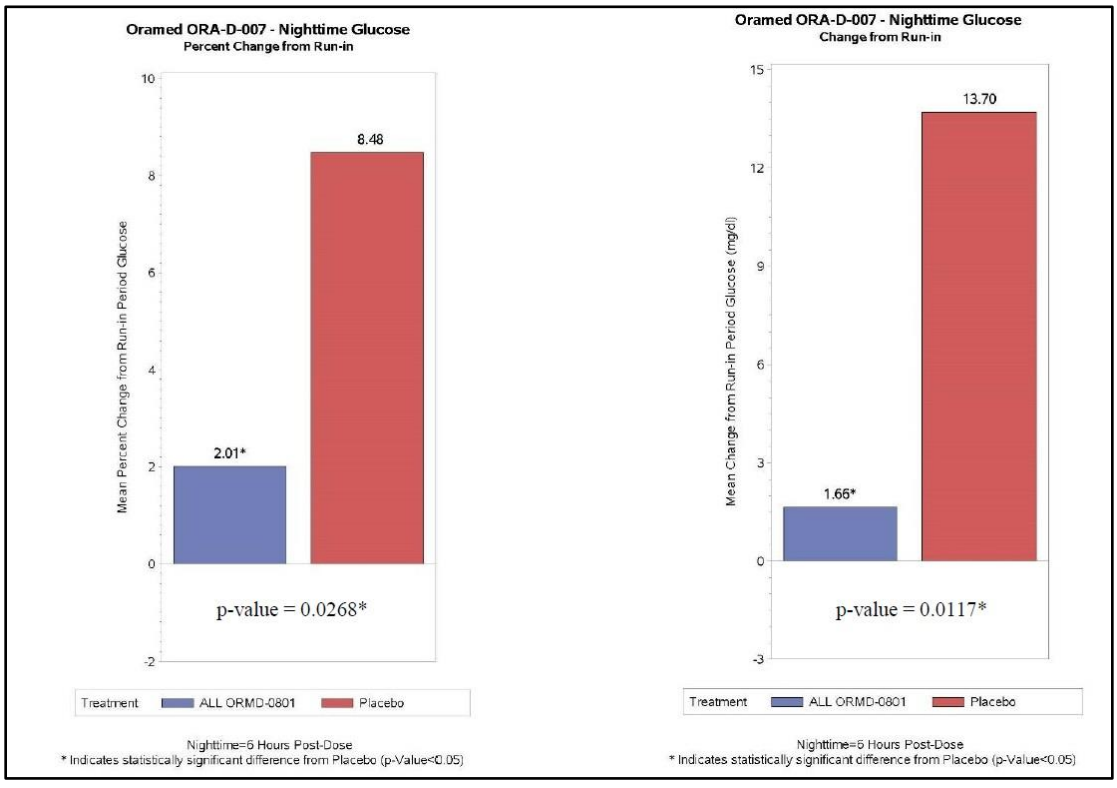
In order to reduce the variability introduced by the extreme outliers that are often present in diabetes studies using CGM data, the 80% trimmed data (data with 10% highest and 10% lowest values for each treatment group removed) will be presented. The trim was pre-defined in the statistical analysis plan and performed in a blinded manner prior to database lock. In our view, investors should note that the data trimming in no way was performed in a post-hoc manner, and therefore does not constitute “data dredging” or “cherry picking”.

Furthermore, the trends that are seen in the 80% trimmed data are also present when the outliers are included. The CGM was applied for seven days in order to obtain a sufficient number of days in which 80% of the glucose measurements are present. The last two days in which at least 80% of the glucose measurements are present are presented in this summary.

Primary Endpoint Data

The mean night-time CGM glucose (defined as six hours after treatment) shows a significant difference in mean percentage change from run-in, between active and placebo (8.48% for placebo vs. 2.01% for ORMD-0801 with a p-value of 0.0268), and a significant difference in mean change from run-in (13.70 mg/dL for placebo vs. 1.66 mg/dL for ORMD-0801 with a p-value of 0.0117). This data is depicted in the bar chart below.

Figure 1: ORMD-0801 Phase 2b Primary Outcome Measure Data—Night-time Glucose



Source: Oramed Pharmaceuticals, Inc.

While in our view the principal critique that can be applied to these findings is that from an absolute magnitude perspective the change in glucose levels is relatively small, we also note that the change provoked by treatment was statistically significant and consistent across multiple blood glucose parameters. In addition, we would stipulate that this was only a 28-day study and that the blood glucose parameters were monitored for a limited period; if the therapy were to be applied for a chronic term (e.g., 24 weeks), we might expect to observe

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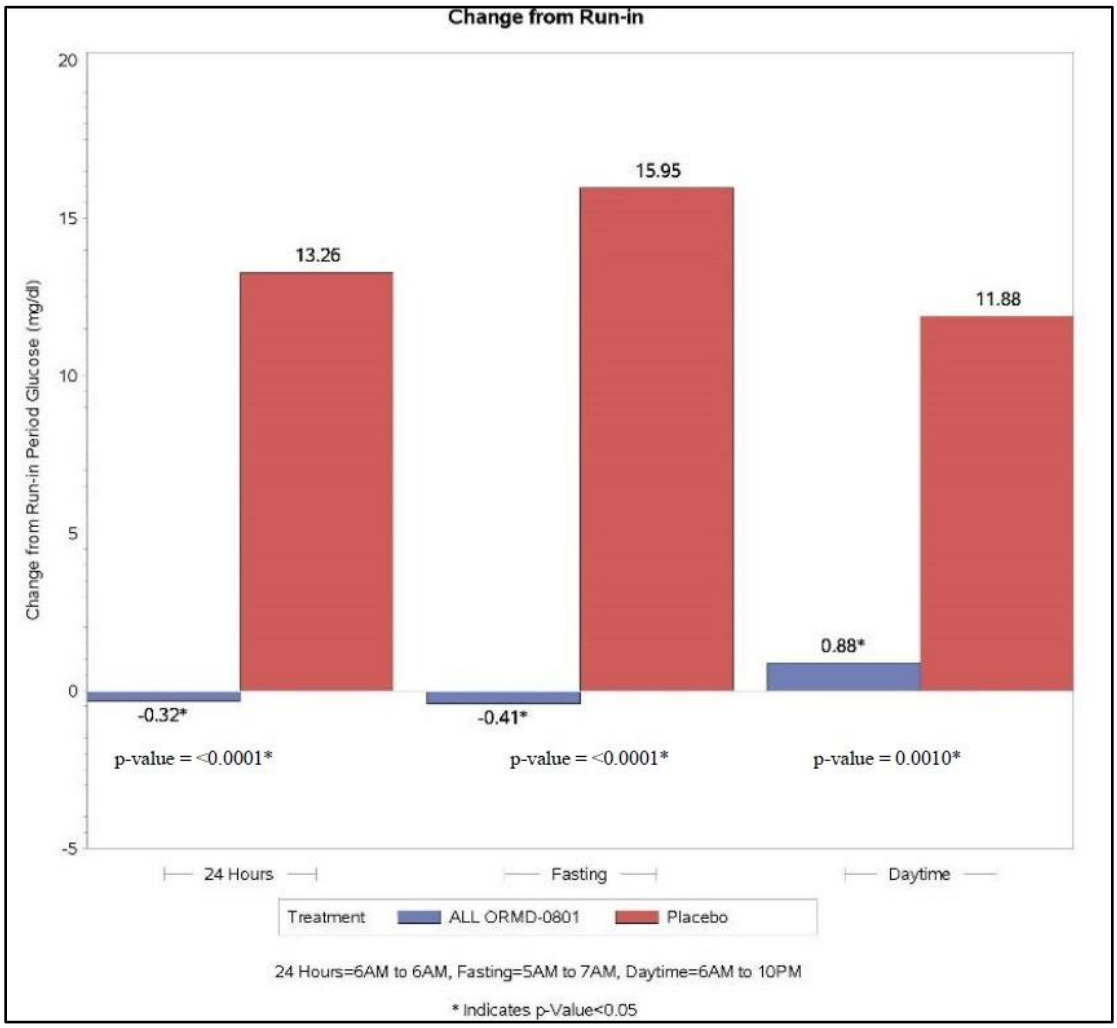
substantially larger changes in glucose levels. As there were no consistent differences between the ORMD-0801 16mg and 24mg treatment groups, the combined active treatment data were used for the presentation of the results.

The mean 24-hour CGM glucose shows a highly significant difference in mean percent change from run-in between active and placebo (7.96% for placebo vs. 0.21% for ORMD-0801 with a p-value of <.0001). There was a highly significant difference in mean change from run-in (13.26 mg/dL for placebo vs. a drop -0.32 mg/dL for ORMD-0801; p<0.0001).

Similarly, the mean fasting CGM glucose (5 AM to 7 AM) shows a highly significant difference in mean percentage change from run-in between active and placebo (10.79% for placebo vs. 1.13% for ORMD-0801 with a p-value of 0.0012) and a significant difference in mean change from run-in (15.95 mg/dL for placebo vs. -0.41 mg/dL for ORMD-0801 with a p-value of <.0001). The mean daytime CGM glucose (6 AM to 10 PM) shows a highly significant difference in mean percent change from run-in between active and placebo (7.03% for placebo vs. 1.11% for ORMD-0801; p=0.0030) and a significant difference in mean change from run-in (11.88 for placebo vs. 0.88 for ORMD-0801; p=0.0010).

Figure 2: ORMD-0801 Phase 2b Trial Additional Glucose Monitoring Endpoint Data



Source: Oramed Pharmaceuticals, Inc.

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Secondary Endpoint Data

There was a statistically significant difference in the percentage change in HbA1c (0.20% for placebo vs. -0.01% for ORMD-0801, with a p-value of 0.0149). It is important to note that, due to the kinetics of change of HbA1c in response to a change in blood glucose control, a four-week study is insufficient to adequately assess the potential positive impact of ORMD-0801 on HbA1c. However, we would consider this initial information encouraging, as it hints towards the possible positive impact of ORMD-0801 on HbA1c that might be fully revealed over a lengthier evaluation window in a larger study.

As expected in a Phase 2b study like this, some of the secondary and exploratory endpoints did not show a statistically meaningful difference between the active groups and the placebo group. These included changes in: morning fasting serum insulin at Day 29; morning fasting C-Peptide; morning fasting triglycerides; weight; serum fasting blood glucose at Day 29 and change in C-reactive protein (CRP).

Results Summary and Perspectives on Future Clinical Development

In summation, therefore, the results of this Phase 2b trial demonstrated that oral administration of multiple bedtime doses of regular human insulin, encapsulated in the form of ORMD-0801 capsules, resulted in a clinically relevant anti-hyperglycemic effect lasting throughout all hours of the day. This is particularly striking, in our view, considering there is no insulin depot as is seen with subcutaneously injected insulins, and, once absorbed, regular human insulin is very rapidly cleared from the bloodstream. The impact of ORMD-0801 on HbA1c is particularly noteworthy, from our perspective. It is important to point out that beyond extrapolating solely from this parameter one can further extrapolate using average daily glucose levels as an acceptable predictor of 90-day HbA1c. The reduction in 24-hour glucose was highly statistically significant. In the placebo arm, 24-hour glucose increased from 173 to 187 mg/dL while in the pooled active treatment arm, the 24-hour glucose remained at baseline of 168 mg/dL throughout the study. These results suggest that Oramed could achieve a further and clinically meaningful reduction in HbA1c in longer trials. In our view, the fact that no clear dose response was observed in this study may be due to a number of factors. While it may be due to lack of clear pharmacokinetic differentiation between the two dose levels studied, it may also very well suggest a mechanistic effect of a liver-directed insulin. This would align with the sustained daylong anti-hyperglycemic effect observed in this study. Oramed is currently planning a short dose response study to get a better understanding of this phenomenon and to fine-tune the selected doses as the company progresses towards a planned Phase 3 trial.

We would draw investors' attention to several key points regarding Oramed's current positioning: (1) the company has now received over half of the total disclosed milestone payments from HTIT, its Chinese partner, totaling $25.5 million (comprising the $3 million upfront payment, the $12 million equity investment at a price per share of over $10, and an additional $10.5 million in milestones associated with the successful completion of the Phase 2b trial of ORMD-0801); (2) the favorable data from the Phase 2b trial of ORMD-0801 should, in our view, be sufficient to support Oramed's ability to request and hold an End-of-Phase 2 meeting with the FDA, which in turn could pave the way for the finalization of the design and subsequent initiation of enrollment in a formal Phase 3 program involving ORMD-0801 in both placebo- and comparator-controlled trials; (3) Oramed currently has *pro forma* cash, in our estimation, of roughly $35 million and should be able to progress through at least the next two years without requiring further capital; and (4) the company's second pipeline candidate, ORMD-0901, continues to be developed and may generate additional data from a robustly-powered Phase 1/2 trial in the first half of next year. Accordingly, we remain bullish on Oramed's long-term prospects and favorably disposed towards the differentiated profile of the company's oral insulin product candidate, as well as its potential ability to deliver an orally-bioavailable glucagon-like peptide 1 (GLP-1) receptor agonist (incretin mimetic) in the form of ORMD-0901, which could be of similar or even greater interest to potential partners.

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Table 2: Oramed Pharmaceuticals, Inc. (ORMP)—Historical Income Statements, Financial Projections

FY end August 31
$ in thousands, except per share data

	2015A					2016E						
	1QA	2QA	3QA	4QA	2015A	1QA	2QA	3QA	4QE	2016E	2017E	2018E
Revenue												
Product revenue	-	-	-	-	-	-	-	-	-	-	-	-
Research and other	-	-	-	-	-	-	125	163	180	468	800	1,000
Total revenue	-	-	-	-	-	-	125	163	180	468	800	1,000
Expenses												
Cost of product and service revenue	-	-	-	-	-	-	-	-	-	-	-	-
Research & development	1,302	1,136	915	1,428	4,781	1,901	1,307	1,718	1,500	6,426	6,200	10,600
Selling and marketing	-	-	-	-	-	-	-	-	-	-	-	-
General and administrative	600	538	719	745	2,602	548	730	555	550	2,383	2,900	4,600
Total expenses	1,902	1,674	1,634	2,173	7,383	2,449	2,037	2,273	2,050	8,809	9,100	15,200
Gain (loss) from operations	(1,902)	(1,674)	(1,634)	(2,173)	(7,383)	(2,449)	(1,912)	(2,110)	(1,870)	(8,341)	(8,300)	(14,200)
Other income/expense												
Financial income	27	38	51	52	168	76	128	137	75	416	246	318
Financial expense	(21)	(1)	-	4	(18)	(17)	(34)	(23)	(23)	(97)	(120)	(120)
Impairment of available-for-sale securities	-	-	-	106	106	(406)	78	84	-	(244)	-	-
Total investment income and other	6	37	51	162	256	(347)	172	198	52	75	126	198
Loss before provision for income taxes	(1,896)	(1,637)	(1,583)	(2,011)	(7,127)	(2,796)	(1,740)	(1,912)	(1,818)	(8,266)	(8,174)	(14,002)
Deferred income tax benefit	-	-	-	1	1	-	-	-	-	-	-	-
Net loss/income	(1,896)	(1,637)	(1,583)	(2,010)	(7,126)	(2,796)	(1,740)	(1,912)	(1,818)	(8,266)	(8,174)	(14,002)
Net loss per share (basic)	(0.19)	(0.16)	(0.15)	(0.18)	(0.67)	(0.24)	(0.14)	(0.15)	(0.14)	(0.65)	(0.62)	(1.01)
Net loss per share (diluted)	(0.19)	(0.16)	(0.15)	(0.18)	(0.67)	(0.24)	(0.14)	(0.15)	(0.14)	(0.65)	(0.62)	(1.01)
Weighted average number of shares outstanding (basic)	10,142	10,482	10,828	11,200	10,663	11,573	12,653	13,119	13,156	12,625	13,281	13,856
Weighted average number of shares outstanding (diluted)	10,142	10,482	10,828	11,200	10,663	11,573	12,653	13,119	13,156	12,625	13,281	13,856

Source: Company reports and Rodman & Renshaw estimates.

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Market Outperform (Buy): The common stock of the company is expected to outperform a passive index comprised of all the common stock of companies within the same sector.

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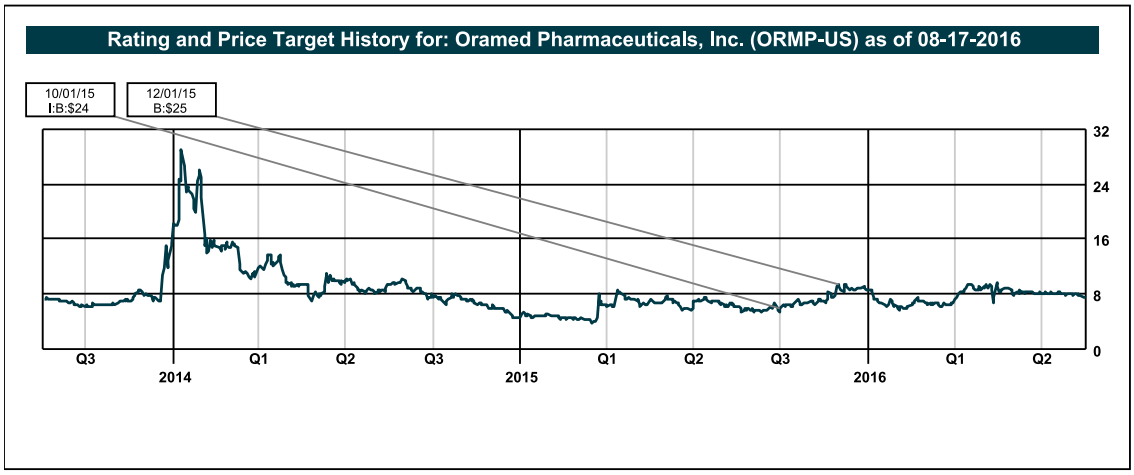

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Distribution of Ratings Table as of August 17, 2016

			IB Service/Past 12 Months	
Ratings	Count	Percent	Count	Percent
Buy	179	95.72%	53	29.61%
Neutral	6	3.21%	2	33.33%
Sell	0	0.00%	0	0.00%
Under Review	2	1.07%	0	0.00%
Total	187	100%	55	29.41%

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