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Oramed Pharmaceuticals Inc. (ORMP-NASDAQ)

ORMP: Second quarter financial results; Strengthens Advisory Board; Positive EoP2 meeting with the FDA

Based on our probability adjusted DCF model that takes into account future revenues from ORMD-0801 and ORMD-0901, ORMP is valued at $23.00 per share. This model is highly dependent on continued clinical success of ORMD-0801 and ORMD-0901 and will be adjusted accordingly based on future clinical results.

Current Price (4/13/2020)	$3.20
Valuation	**$23.00**

OUTLOOK

Oramed Pharmaceuticals Inc. (ORMP) is developing multiple products based on the company's technology that allows for oral administration of proteins. The lead development product, ORMD-0801, is an oral insulin being tested in patients with both type 1 and type 2 diabetes. The company recently announced successful results from the 90-day, dose-ranging Phase IIb clinical trial. In addition, results from a pharmacokinetic study of an oral GLP-1 analog of exenatide and the first cohort in an exploratory study of ORMD-0801 in NASH patients are anticipated in the near term.

SUMMARY DATA

52-Week High	**$5.74**
52-Week Low	**$2.43**
One-Year Return (%)	**-23.61**
Beta	**1.89**
Average Daily Volume (sh)	**95,202**
Shares Outstanding (mil)	**23**
Market Capitalization ($mil)	**$73**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**3**
Insider Ownership (%)	**21**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-34.0**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2019 Estimate	**-3.6**
P/E using 2020 Estimate	**-3.5**

Risk Level	**Average**
Type of Stock	**Small-Blend**
Industry	**Med Products**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2019	0.7 A	0.7 A	0.7 A	0.7 A	2.7 A
2020	0.7 A	0.7 A	0.7 A	0.7 A	2.7 A
2021					2.8 E
2022					2.8 E

Earnings per Share

	Q1 (Nov)	Q2 (Feb)	Q3 (May)	Q4 (Aug)	Year (Aug)
2019	-$0.25 A	-$0.21 A	-$0.23 A	-$0.12 A	-$0.82 A
2020	-$0.25 A	-$0.21 A	-$0.23 A	-$0.12 A	-$0.79 A
2021					-$0.91 E
2022					-$0.95 E

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WHAT'S NEW

Second quarter financial results; Strengthens Advisory Board; Positive EoP2 meeting with the FDA

Financial Update

Oramed reported second quarter financial results on 6th April, 2020 and provided a business update. The company reported revenues of $674k for the quarter. These revenues are related to the license agreement with Hefei Tianhui Incubator of Technologies Co., Ltd. (HTIT) signed in 2015 and are recognized through June 2023.

R&D expenses for the quarter was $3.3 million, which was related to the completion of Phase IIb clinical trial (including regulatory expenses) and anticipatory Phase III trial. As Phase III clinical studies are expected to commence in the near-term, we expect R&D spend to increase during the year. G&A expenses came in around $1.3 million. The company recorded a net loss of about $3.7 million.

During the quarter, Oramed also received close to $6 million from the exercise of warrants and options. The company exited the quarter with $29 million in cash, short-term bank deposits and marketable securities. Subsequent to quarter end, Oramed raised additional capital in the amount of $21 million. The company's current cash balance is roughly $50 million which offers runway for the next 18 months.

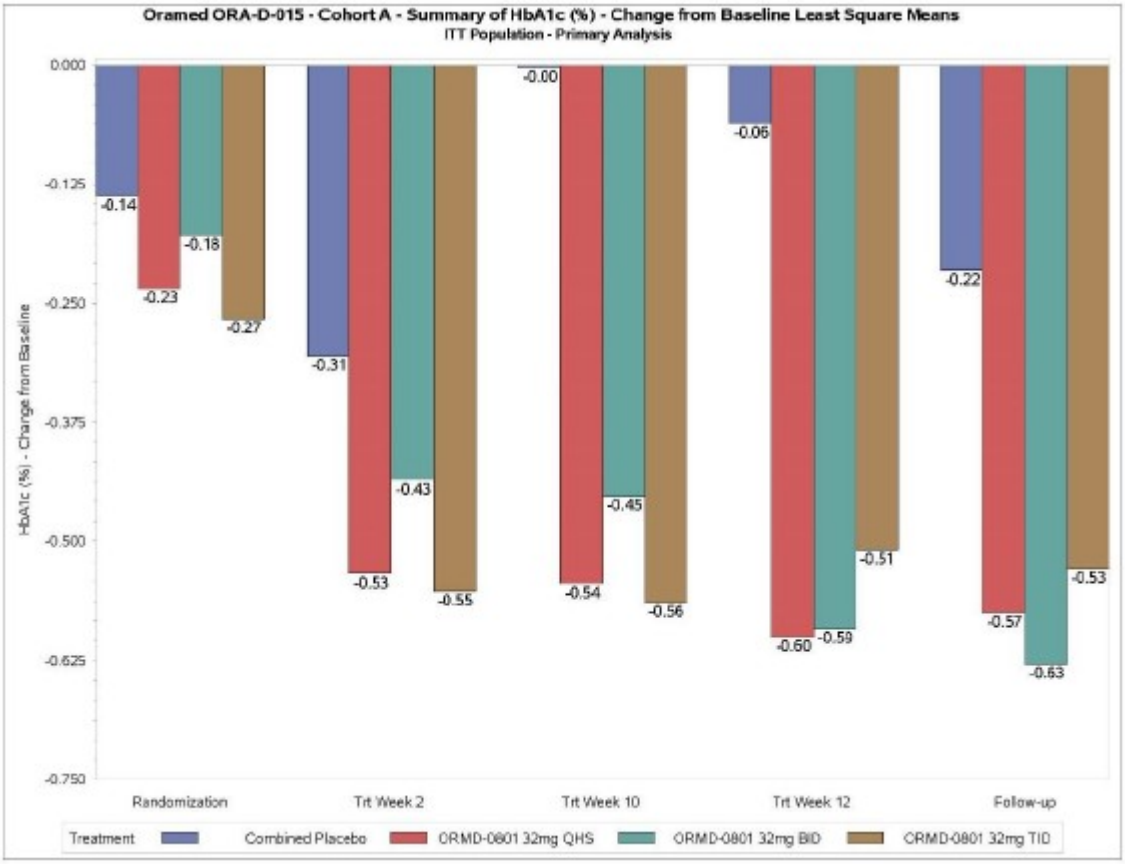
Business Update

Results of the Phase 2b Trial

The primary objective of the Phase II study was to explore therapeutic efficacy in patients and more importantly, determine the dose(s) and regimen for Phase III trials. A double blind, randomized 90-day dosing trial (Phase 2b), which was funded by ORMD, was designed to evaluate the efficacy of ORMD-0801 in decreasing HbA1C levels, a key clinical measure of blood sugar. On September 17, 2019, Oramed announced that the last patient from the first cohort of the Phase 2b clinical trial of ORMD-0801 had completed treatment.

Cohort A: A total of 269 U.S. based patients with more than 6-months history of T2D and HbA1C levels between 7.5% and 9.6%, were enrolled in the Phase 2b trial. Approximately 70% of the randomized patients were on metformin alone, or metformin with up to two additional oral antihyperglycemic agents. Patients were randomized into three groups (~80 patients in each arm) to assess dosing frequency: once-daily (32mg/day), twice-daily (64mg/day), thrice-daily (96mg/day). Approximately 1/3rd of patients in each treatment arm were assigned to placebo. Two hundred nine (209) patients completed treatment to the 12-week endpoint and were included in the data analysis (24 subjects did not complete the full 12 weeks of treatment). In addition, due to evidence of treatment-by-center interaction, two sites (36 patients (13.4% of enrolled subjects)) were excluded from the statistical analysis.

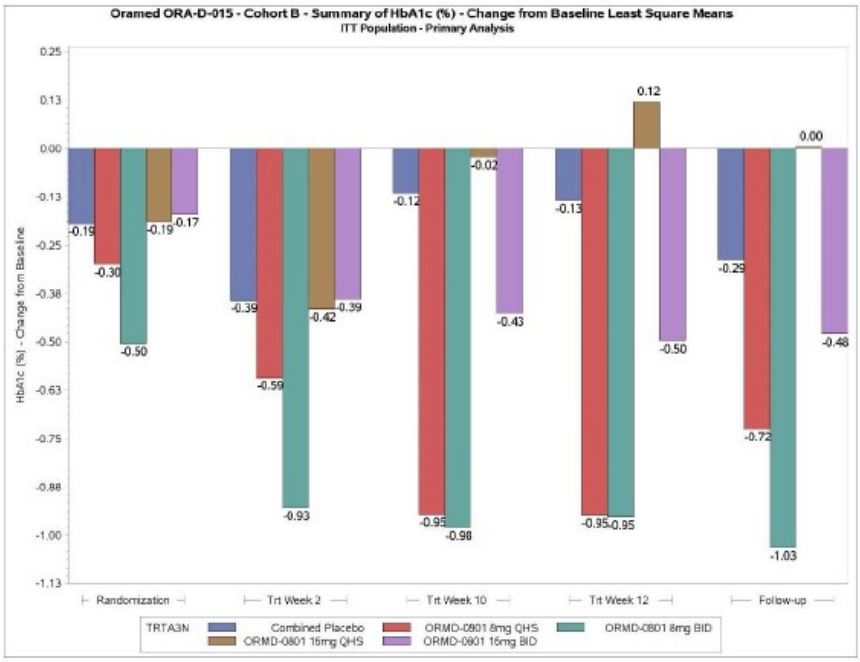
The key outcomes to be assessed were reduction in HbA1c levels and safety. The secondary end points included safety assessed by hypoglycemia, change from baseline in glycemic parameters measured using outpatient CGM and change in weight from baseline to week 12 of the treatment period.



(Source: oramed.com)

Results demonstrated that 32mg dosed once and twice daily resulted in HbA1c reduction of 0.60% (0.54% with placebo adjustment, p-value 0.036) and 0.59% (0.53% with placebo adjustment, pvalue 0.042) by 12 weeks. The thrice-daily arm did not meet statistical significance (p-value 0.093). ORMD-0801 demonstrated an excellent safety profile with no serious drug-related adverse events. Results also demonstrated no increase in hypoglycemic events and no weight gain when compared to placebo.

Cohort B: The company has also initiated a second cohort of patients in a 90-day, double blind, randomized, multi-center study designed to evaluate the potential efficacy of multiple lower doses of ORMD-0801 with once daily higher dosing. The study was designed to identify the optimal dose of ORMD-0801 for the Phase 3 trial. In the low-dose second cohort, 78 patients have been randomized into five groups: 8 mg dosed once-daily; 8 mg dosed twice-daily; 16 mg dosed once-daily; 16 mg dosed twice-daily; and placebo dosed twice-daily. About 60% of the randomized patients were on two or more glucose-lowering medication. As anticipated, Oramed announced the results from the second cohort on February 27, 2020.



(Source: oramed.com)

Patients randomized in the trial treated with 8 mg of ORMD-0801 once daily achieved an observed mean reduction of 1.29% from baseline and a least square mean reduction of 0.95% from baseline, or 0.81% adjusted for placebo (p value = 0.028). Patients who had HbA1C readings above 9% at baseline and received 8 mg of oral insulin once daily experienced a 1.26% reduction in HbA1C levels by week 12. Treatment with ORMD-0801 at all doses demonstrated an excellent safety profile, with no serious drug-related adverse events and no increased frequency of hypoglycemic episodes or weight gain compared to placebo. The side-effect profile was no different from those that received a placebo. In particular, 8 mg once-daily and 16 mg twice-daily group reported no hypoglycemic events. Serum glucose levels were very consistent with HbA1C levels.

Cohort A - Change from Baseline at 12 weeks			
Baseline HbA1 c Values > 9 (92 Subjects)		**Baseline HbA1 c Values <= 9 (117 Subjects)**	
ORMD-0801 32mg QHS Placebo Adjusted	-0.72	ORMD-0801 32mg QHS Placebo Adjusted	-0.41
ORMD-0801 32mg BID Placebo Adjusted	-0.65	ORMD-0801 32mg BID Placebo Adjusted	-0.52
ORMD-0801 32mg TID Placebo Adjusted	-0.54	ORMD-0801 32mg TID Placebo Adjusted	-0.41
Cohort A&B - Change from Baseline at 12 weeks			
Baseline HbA1 c Values > 9 (118 Subjects)		**Baseline HbA1 c Values <= 9 (148 Subjects)**	
ORMD-0801 8 mg QD Placebo Adjusted	-1.26	ORMD-0801 8 mg QD Placebo Adjusted	-0.56
ORMD-0801 8 mg BID Placebo Adjusted	-1.03	ORMD-0801 8 mg BID Placebo Adjusted	-0.71
ORMD-0801 16 mg QD Placebo Adjusted	-0.05	ORMD-0801 16 mg QD Placebo Adjusted	0.54
ORMD-0801 16 mg BID Placebo Adjusted	-0.93	ORMD-0801 16 mg BID Placebo Adjusted	0.34

(Source: oramed.com)

The table above shows change in placebo-adjusted HbA1C values from baseline at 12 weeks for Cohort A and Cohort A&B together. In Cohort A, HbA1C levels post treatment (with 32mg dosed once, twice or thrice daily) were significantly lower in patients having baseline HbA1C values greater than 9, which is as expected. For those having HbA1C values less than or equal to 9, 32mg dosed once twice or thrice daily saw a smaller drop in values. When looking at values in Cohorts A and B, for those patients having baseline HbA1C values greater than 9, the placebo-adjusted numbers demonstrated significant change except for 16mg once daily dose that showed no change in values. Especially, the 8mg once daily

showed an impressive reduction in levels by 1.26%. For those having HbA1C values less than or equal to 9, 8mg once or twice daily saw a smaller drop in values whereas the 16mg dose did not see a change.

ORMP-0801 has shown clinical efficacy. In fact, at 12 weeks after baseline treatment, we see significantly higher reduction in HbA1C levels among patients who were treated with 8mg doses as compared to the 16mg or 32mg doses. The 16mg twice daily and 32mg thrice daily showed reduction in levels after adjusting for placebo but were not statistically significant. It was further observed that, the increase in frequency of dosing did not show significant improvement in HbA1C levels. The present study further demonstrated no significant change in serum glucose levels at 12 weeks from baseline.

An effective oral form of insulin has benefits in terms of encouraging compliance and treatment adherence among patients. Physiologically such a dosage form replicates the natural route of insulin secretion and absorption through the portal vein and targets the liver directly. However, developing an oral form has, thus far, been challenging to the research community. Only a fraction of insulin administered by injections reaches the liver, often causing excess sugar to be stored in fat and muscle which results in weight gain. While the development of oral insulin has been elusive, Oramed has developed their candidate that overcomes the barriers to absorption and protect the insulin while transiting through the gastrointestinal (GI) tract. Due to direct engagement of the liver and resumption of its role in glucose metabolism, Oramed's candidate has likely offered advantages with plausible beneficial clinical ramifications, including no change in weight gain associated with systemic insulin therapy and reducing the risk of hypoglycemia. In normal patients, glucose homeostatis is maintained. A transient increase in insulin secretion occurs just before dawn to control hepatic glucose production and prevent hyperglycemia. A major challenge T2D patients face is that they experience abrupt increases in fasting levels of plasma glucose or insulin requirements or both at dawn. One of the goals in treating T2D patients is to reestablish normal glycemic levels in the morning to lower the mean daily blood glucose and HbA1c levels. By improving night-time glucose levels, a person with diabetes can start the day with improved metabolic condition, which enables better control of blood glucose levels throughout the day. ORMD-0801 has demonstrated an excellent safety profile, specifically with regards to hypoglycemic events.

While many other competing firms have developed candidate drugs that fell by the wayside, ORMD-0801 has demonstrated efficacy that has not been achieved before. It also offers the secondary benefit of not having to inject oneself with medication every so often. ORMD-0801 could prove to be a game-changer for the more than 100 million Americans living with diabetes. During the investor call, Dr. Fleming expressed excitement over the positive clinical evidence of ORMD-0801.

Insulin drugs tend to have a narrow therapeutic index and a small difference in the dosage could result in a therapeutic benefit or toxicity. For instance, an overdose of insulin may cause severe hypoglycemia resulting in brain damage or even death. ORMD-0801 has shown safety and efficacy and is promising to address the unmet need in the treatment of diabetes. Although ORMD-0801 could be packaged at multiple doses, the outcome of the trial indicates that 8 mg dosed once-daily provided good overall clinical benefit. The study indicated that dosing frequency had little effect on the efficacy of ORMD-0801 T2D patients. A lower dose administered once daily also provides economic benefit to patients. Perhaps, the 8mg of insulin could prove to be a "one-size-fits-all" dose despite the enormous genetic variation among T2D patients. However, this is yet to be decided based on Phase 3 studies. Additionally, there is opportunity to use it as a treatment for T1D patients and even in prediabetics as a preventive medication.

The Phase IIb trial investigating ORMP-0801, an oral insulin capsule as a treatment for diabetes, achieved the primary end point (reduction in HbA1c levels compared to placebo at week 12) successfully. Subsequently, the company met with the regulatory authorities in February for an End-of-Phase-II (EoP2) meeting. The meeting with the FDA was productive and has clarified the path forward for ORMD-0801 to

obtain a future NDA submission. The focus of this meeting was to confirm two key elements to the continued development of ORMD-0801. First, the FDA provided detailed guidance regarding the Chemistry Manufacturing and Control (CMC) of ORMD-0801. Secondly, the company expects to have another meeting with the regulatory agency to discuss Phase III trial design. This meeting represents the completion of another important milestone for Oramed. Management is also planning to obtain marketing approval in Europe and therefore intends to meet with the European Medicines Agency (EMA) regarding the Phase III study design. We believe that the success of this clinical study could fuel a partnership from a larger pharmaceutical company.

Due to SARS-CoV-2 outbreak causing COVID-19, several clinical studies have been suspended and have not commenced as originally planned. Oramed's exploratory trials have also been delayed due to the cascade of effects from COVID-19. While we are disappointed with the current situation, we understand that the company intends to protect the safety of study participants as well as staff at clinical trial sites and ensure regulatory compliance. We think that studies could commence once there is sufficient control of the spread of virus.

Exploratory NASH Trial
Oramed initiated an exploratory proof-of-concept study to evaluate ORMD-0801 in patients suffering from nonalcoholic steatohepatitis (NASH). The study will test the ability of ORMD-0801 to reduce liver fat, inflammation, and fibrosis in NASH patients. The company has expanded the trial to 30 patients and we expect the data from this study in the near term.

NASH is inflammation and damage to the liver brought about by a buildup of fat and is the most severe form of nonalcoholic fatty liver disease (NAFLD). It is often a "silent" liver disease as most patients with NASH feel well and are not aware that they have a liver problem. However, NASH can be severe and ultimately lead to cirrhosis, liver failure, and hepatocellular carcinoma. NASH is currently estimated to affect two to five percent of the U.S. population (NIDDK) with the global market estimated to reach $20 billion by 2025 (Allied Market Research).

Oral Leptin Trial
Oramed is planning to conduct an exploratory, proof-of-concept trial to evaluate an oral leptin product for the reduction of glucagon in patients with T1D. Leptin is a 16-kDa peptide hormone that is primarily produced by adipose tissue. It is an essential hormone for maintaining energy homeostasis and body weight, with leptin resistance identified as a key risk factor for obesity (Zhou et al., 2013). The single-dose safety trial is scheduled to begin later this year in 10 patients with T1D and we anticipate topline results soon after. The ultimate goal of the project is to address weight loss in overweight patients.

Strengthened Advisory Board…
In the beginning of the year, Oramed bolstered its advisory board with the addition of Dr. Alexander Fleming and Dr. Julio Rosenstock. Oramed has appointed these two strategic advisors with relevant experience to deepen the board's expertise.

Dr. Fleming previously held various positions at the FDA in which he was responsible for the therapeutic areas of diabetes and other metabolic and endocrine disorders. He led reviews of landmark approvals, including metformin and the first statin, insulin analog, PPAR-agonist, and growth hormone for non-GH deficiency indications. Dr. Fleming oversaw clinical review of the earliest biotech products, including human insulin. Dr. Fleming also helped to shape FDA policies and practices related to therapeutic review and regulatory communication.

Dr. Rosenstock's clinical research efforts focus on exploring novel agents and therapeutic strategies to improve glycemic control. Over the last 30 years, he has participated in hundreds of clinical trials and has had an active role in the development of new oral agents and insulin preparations acting often as a lead

clinical investigator and scientific advisor. Dr. Rosenstock is a member of the National Board of Directors of the American Diabetes Association (ADA) and is currently an Associate Editor of Diabetes Care.

Conclusion and Valuation

We're glad to see the results for the Phase IIb HbA1c trial in patients with T2D. While we anticipate data from a couple of other studies in 2020, we view the data from the Phase IIb study of ORMD-0801 as the most important for the company. It seems likely that the company might jumpstart partnership negotiations since we believe Oramed will seek a development partner before moving into a Phase III trial.

We value Oramed using a probability adjusted discounted cash flow model that takes into account potential future revenues from ORMD-0801 and ORMD-0901. We currently model for approval of ORMD-0801 in 2024 with first sales in 2025 and approval of ORMD-0901 in 2025 with first sales in 2026. We estimate for peak U.S. sales of ORMD-0801 of approximately $400 million and peak U.S. sales of ORMD-0901 of approximately $500 million. Using a 12% discount rate and a 64% probability of approval for ORMD-0801 and a 45% probability of approval for ORMD-0901 leads to a net present value for those two programs of $213 million and $152 million, respectively. When including the current cash total, potential cash from warrant exercises, and dividing by the fully diluted share count leads to a net present value for Oramed of approximately $23 per share.

PROJECTED FINANCIALS

Oramed Pharmaceuticals Inc. (Fiscal Year ends Aug. 31)	FY2018 A	FY2019 A	Q1 A	Q2 A	Q3 E	Q4 E	FY2020 E	FY2021 E	FY2022 E
License Revenue	$2.4	$2.7	$0.7	$0.7	$0.7	$0.7	$2.8	$2.8	$2.8
YOY Growth	-	-	-	-	-	-	-	-	-
Grant/ Contract Revenue	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-
ORMD-0801	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-
ORMD-0901	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$2.4**	**$2.7**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.8**	**$2.8**	**$2.8**
YOY Growth	*0%*	*10%*	*0%*	*1%*	*3%*	*3%*	*4%*	*0%*	*0%*
Cost of Revenue	$0.1	$0.1	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Gross Income	**$2.5**	**$2.6**	**$0.7**	**$0.7**	**$0.7**	**$0.7**	**$2.8**	**$2.8**	**$2.8**
Gross Margin	*103.5%*	*96.7%*	*96.7%*	*96.7%*	*96.7%*	*96.7%*	*100.0%*	*100.0%*	*100.0%*
Research & Development	$12.0	$13.5	$2.0	$3.3	$2.0	$3.5	$16.0	$18.0	$20.0
General & Administrative	$4.1	$3.7	$1.1	$1.4	$1.2	$1.3	$5.0	$7.5	$7.5
Other Expenses	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Operating Income	**($13.5)**	**($14.6)**	**($2.4)**	**($4.0)**	**($2.5)**	**($4.1)**	**($18.2)**	**($22.7)**	**($24.7)**
Operating Margin	-	-					-	-	-
Other Income (Net)	$1.1	$0.6	$0.1	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	**($12.7)**	**($14.1)**	**($2.5)**	**($3.7)**	**($2.5)**	**($4.1)**	**($18.2)**	**($22.7)**	**($24.7)**
Net Taxes (benefit)	$0.0	$0.3	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*	*0.0%*
Reported Net Income	**($12.7)**	**($14.4)**	**($2.5)**	**($3.7)**	**($2.5)**	**($4.1)**	**($18.2)**	**($22.7)**	**($24.7)**
Net Margin	-	-					-	-	-
Reported EPS	**($0.86)**	**($0.82)**	**($0.15)**	**($0.16)**	**($0.11)**	**($0.18)**	**($0.79)**	**($0.91)**	**($0.95)**
YOY Growth	-	-					-	-	-
Basic Shares Outstanding	14.9	17.5	17.5	23.1	23.1	23.1	23.1	25.0	26.0

Source: Zacks Investment Research, Inc. *Anita Dushaynth, PhD*

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HISTORICAL STOCK PRICE



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