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Viking Therapeutics, Inc. (VKTX-NASDAQ)

VKTX: Podium Presentation at EASL…

Based on our probability adjusted DCF model that takes into account potential future revenues of VK5211, VK2809, and VK0214, VKTX is valued at $24/share. This model is highly dependent upon continued clinical success of those compounds and will be adjusted accordingly based upon future clinical results.

Current Price (02/28/20)	$5.96
Valuation	**$24.00**

OUTLOOK

Viking Therapeutics, Inc. (VKTX) announced financial results for the fourth quarter and full year 2019 and provided a business update. The company will be presenting additional data from the Phase 2 clinical trial of VK2809 in a podium presentation on April 17 at the 2020 International Liver Congress, which is hosted by the European Association for the Study of the Liver (EASL). The Phase 2b VOYAGE trial of VK2809 in patients with biopsy-confirmed NASH is underway at U.S. clinical sites and we anticipate ex-U.S. sites opening throughout the upcoming year. IND-enabling work is continuing for VK0214 and we anticipate an IND being filed in the second quarter of 2020 with the initiation of a Phase 1 trial shortly thereafter.

SUMMARY DATA

52-Week High	**$10.63**
52-Week Low	**$5.96**
One-Year Return (%)	**-29.13**
Beta	**2.35**
Average Daily Volume (sh)	**991,228**
Shares Outstanding (mil)	**73**
Market Capitalization ($mil)	**$432**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**55**
Insider Ownership (%)	**3**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2018 Estimate	**-9.6**
P/E using 2019 Estimate	**-8.2**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	0 A	0 A	0 A	0 A	0 A
2020	0 E	0 E	0 E	0 E	0 E
2021					0 E
2022					0 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2019	-$0.07 A	- $0.11 A	-$0.08 A	-$0.10 A	-$0.36 A
2020	-$0.11 E	-$0.13 E	-$0.15 E	-$0.16 E	-$0.54 E
2021					-$0.75 E
2022					-$0.89 E

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WHAT'S NEW

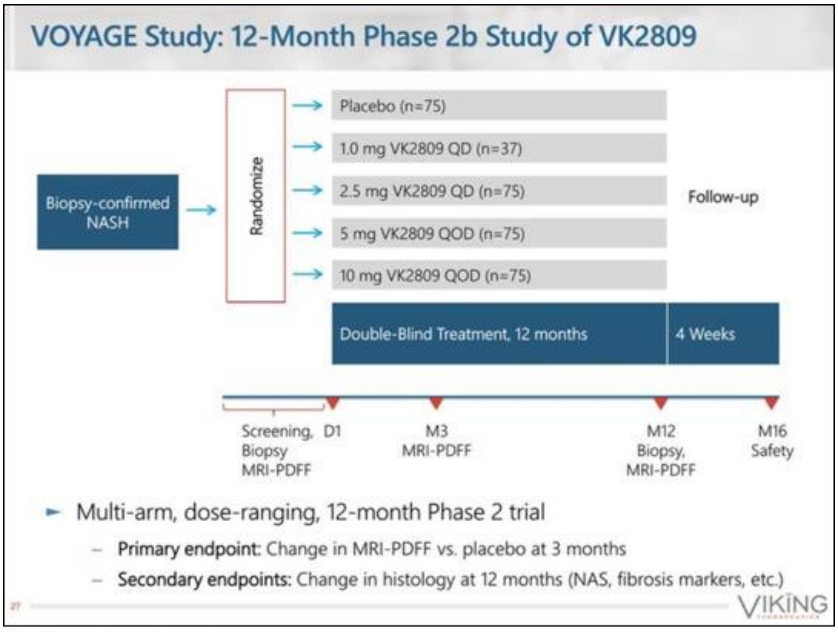
Business Update

Podium Presentation at EASL

On February 26, 2020, Viking Therapeutics, Inc. (VKTX) announced that an abstract describing additional data from the Phase 2 trial of VK2809 in patients with non-alcoholic fatty liver disease (NAFLD) and hypercholesterolemia was selected for an oral presentation at the 2020 International Liver Congress, which is hosted by the European Association for the Study of the Liver (EASL). The presentation will take place on April 17, 2020. While full details of the abstract were not disclosed, the company did say that it will include data for patients that had a liver MRI performed at week 16 of the trial (4 weeks after dosing stopped) along with an examination of various subsets and patient characteristics.

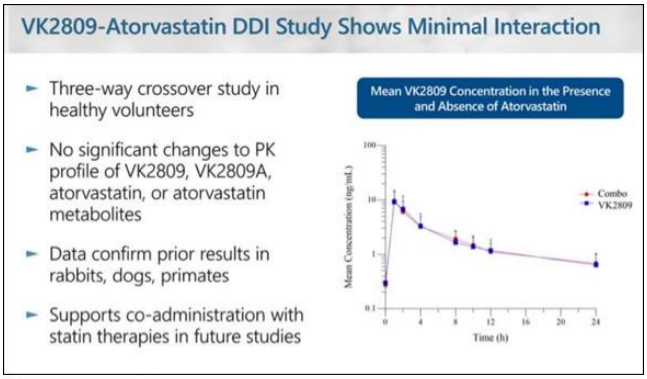
Phase 2b VOYAGE Trial Underway

In November 2019, Viking announced that the Phase 2b VOYAGE trial of VK2809 in patients with biopsy-confirmed nonalcoholic steatohepatitis (NASH) is underway. The randomized, double blind, placebo-controlled trial is expected to enroll approximately 340 patients with fibrosis ranging from stages F1 to F3 across five treatment groups: 1 mg VK2809 daily, 2.5 mg VK2809 daily, 5 mg VK2809 every other day, 10 mg VK2809 every other day, or placebo. We expect approximately 75 patients per arm for the 2.5 mg, 5 mg, 10 mg, and placebo groups and approximately 40 patients in the 1 mg arm. There will be a total of approximately 70 centers enrolling patients in the US and we expect approximately 10-15 ex-U.S. centers opening throughout the upcoming year. An overview of the trial is given below.



Source: Viking Therapeutics, Inc.

Importantly, there were no restrictions placed on patient enrollment like those that were in place for the Phase 2 trial of VK2809 in patients with hypercholesterolemia and fatty liver disease. In that trial, there were restrictions on enrolling diabetic patients and those on statin-type lipid-lowering medications. For the Phase 2b trial, there are no such restrictions, thus the company will be free to enroll patients with comorbidities such as Type 2 diabetes, obesity, and metabolic syndrome, as well as those taking certain cholesterol-lowering medications, including statins. The company previously presented data from a drug-drug interaction study of VK2809 and atorvastatin in healthy volunteers showing that there is no significant change to the pharmacokinetic (PK) profile of VK2809 when dosed in combination with atorvastatin. This is important as many NASH patients are on lipid-lowering medications, thus there should be no issue with treating those patients with VK2809.



Source: Viking Therapeutics, Inc.

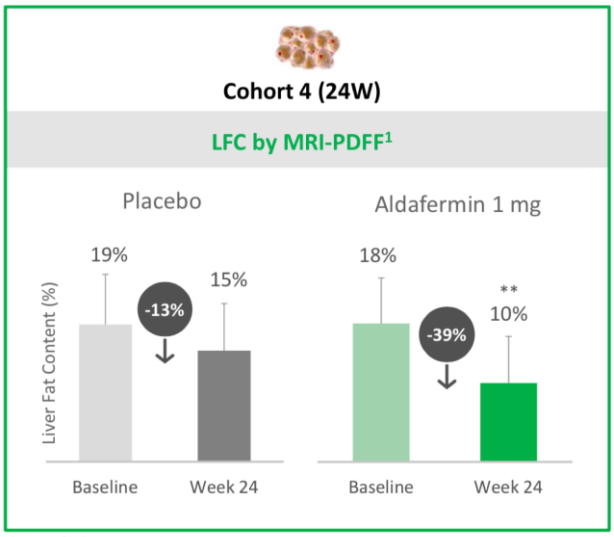
The primary endpoint of the trial is the 12-week change in liver fat content assessed by magnetic resonance imaging proton density fat fraction (MRI-PDFF) for those treated with VK2809 compared to placebo. A key secondary outcome measure is histological changes assessed by liver biopsy following 52 weeks of dosing. While the trial is currently only approved for 6-months of dosing, we anticipate the company submitting the 12-month animal toxicology data to the FDA very soon and following clearance by the FDA patients will receive the full 52 weeks of dosing.

With 340 patients targeted for the study we estimate that enrollment will take approximately 12 months, however once the initial enrollment numbers are known later this year we should have a better sense for when full enrollment will occur. If the trial is enrolled by the end of 2020, we estimate 12-week MRI-PDFF data would be available in the first half of 2021 and full 52-week biopsy data would be available in the first half of 2022.

NGM Data Shows Lowering Liver Fat Leads to Histological Improvements

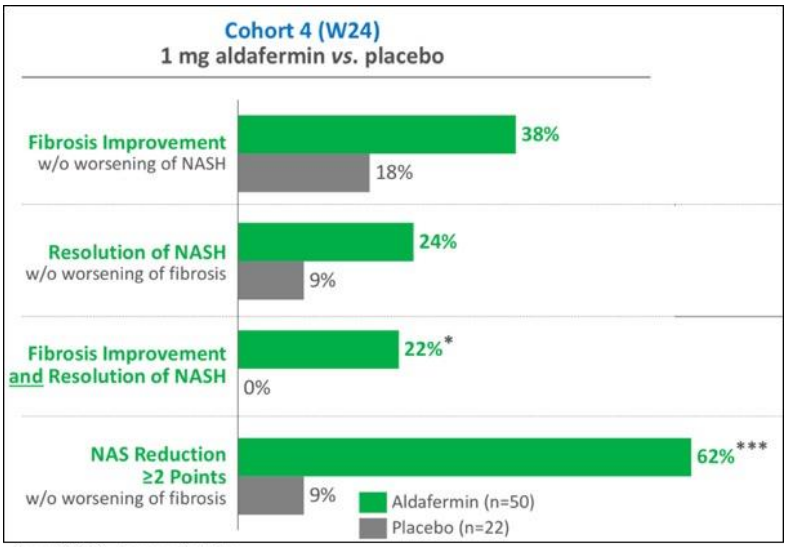
On February 24, 2020, NGM Biopharmaceuticals, Inc. (NGM) announced positive topline liver histology data from the 24-week Phase 2 Cohort 4 study of aldafermin in biopsy-confirmed NASH patients. Aldafermin is an engineered variant of fibroblast growth factor 19 (FGF19), a human protein hormone that has effects on bile acid synthesis, glucose metabolism, and lipid metabolism. The Phase 2 trial is a multi-center, double blind, randomized, placebo controlled study evaluating the efficacy and safety of 1 mg once daily subcutaneous injections of aldafermin over 24 weeks of treatment in four different cohorts. Cohort 4 enrolled 78 patients that were randomized 2:1 to receive aldafermin (n=53) or placebo (n=25). The primary endpoint of the trial was the effect on absolute liver fat content (LFC) as measured by MRI-PDFF with secondary endpoints examining relative changes in LFC, liver function biomarkers, and liver histology.

The following figure shows that the study achieved its primary endpoint, as treatment with aldafermin resulted in a statistically significant absolute least square (LS) mean reduction in LFC of 8% (P<0.01) and a statistically significant LS mean relative reduction in LFC of 39% (P<0.01), compared to reductions of 3% and 13%, respectively, in the placebo arm.



Source: NGM Biopharmaceuticals, Inc.

The decrease observed in liver fat correlated with improvements in liver histology. The following figure shows that treatment with aldafermin led to clinically meaningful improvements at 24 weeks in fibrosis and in resolution of NASH compared to placebo. Fibrosis improvement of ≥1 stage with no worsening of NASH was seen in 38% of patients treated with aldafermin compared to 18% of placebo-treated patients. NASH resolution with no worsening of fibrosis was seen in 24% of patients in the aldafermin group compared to 9% in the placebo group. NGM also showed that 22% of patients in the aldafermin group achieved the composite endpoint of both fibrosis improvement and resolution of NASH compared to 0% of placebo patients, which was a statistically significant result. According to the FDA's draft guidance, each of those outcomes is an approvable endpoint for a pivotal trial.



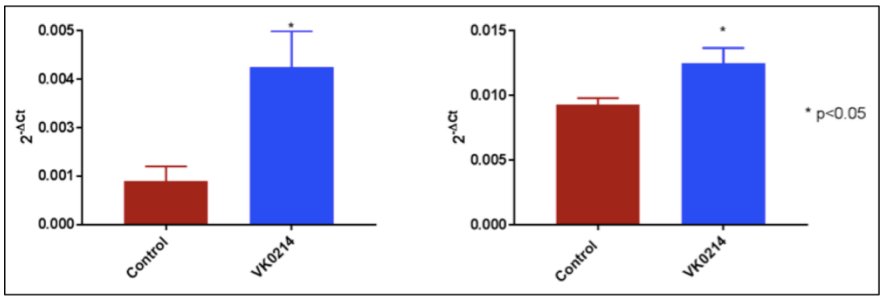
Source: NGM Biopharmaceuticals, Inc.

We believe the most important takeaway from NGM's data is that a robust decrease in liver fat (8% absolute and 39% relative reduction) can lead to a clinically meaningful improvement in liver histology. In the Phase 2 trial, VK2809 showed a composite 9.4% absolute reduction and 56% relative reduction in liver fat, thus based on NGM's data we believe there is a very good chance that similar reductions in liver fat in the ongoing Phase 2b VOYAGE trial will translate to meaningful improvements in liver histology.

VK0214 IND to be Filed in 2Q20

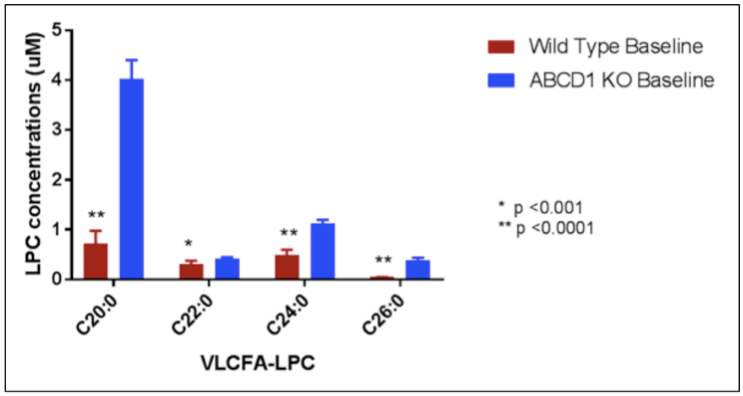
VK0214 is being developed for the treatment of X-linked adrenoleukodystrophy (X-ALD), an orphan neurodegenerative disease that affects approximately 8,000 individuals in the U.S. and 12,000 in Europe. In contrast to VK2809, VK0214 is a TRβ agonist that is activated by carboxyesterases that are ubiquitously expressed in the body. The drug also has a different pharmacokinetic and pharmacodynamic profile than VK2809, thus potentially making the drug more suitable for a disease such as X-ALD, which is more diffuse than NASH.

X-ALD is caused by a mutation(s) in the *ABCD1* gene, which encodes the adrenoleukodystrophy protein (ALDP). ALDP is responsible for transporting very long chain fatty acids (VLCFAs) into peroxisomes for degradation, thus without proper ALDP function the VLCFAs accumulate to toxic levels. The theory behind using VK0214 to treat X-ALD is that it increases the expression of ALDR (encoded by the *ABCD2* gene), which is also a VLCFA transporter, thus compensating for the loss of ALDP. The following graph shows that VK0214 induces the expression of the *Abcd2* gene in mice.



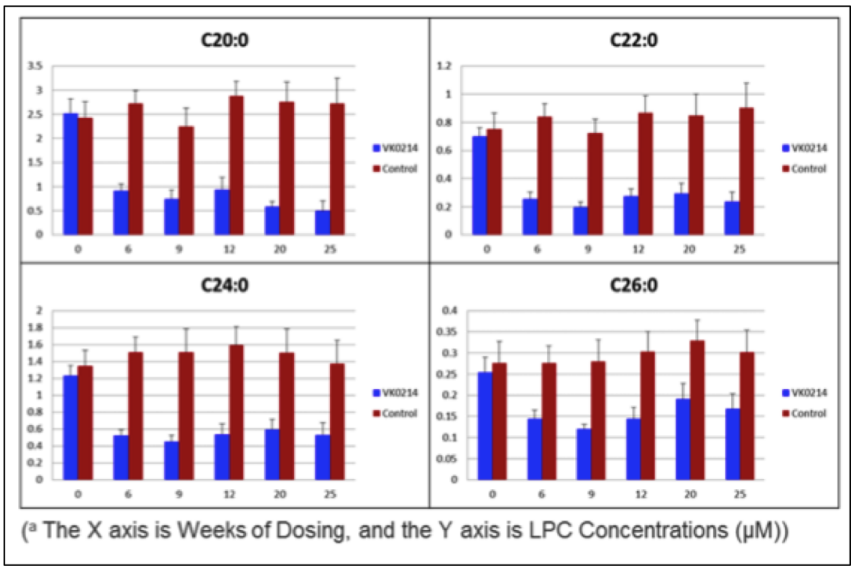
Source: Masamune *et al.*, 2017

The company previously presented positive *in vivo* results at the 87th Annual Meeting of the American Thyroid Association from a study involving the *Abcd1* knock-out (KO) mouse model, which while not displaying the inflammatory characteristics of the more severe forms of X-ALD, does recapitulate a biochemical phenotype similar to those with adrenomyeloneuropathy (AMN), the less severe form of X-ALD. As shown in the following figure, *Abcd1*$^{-/-}$ mice have elevated levels of VLCFAs compared to wildtype mice.



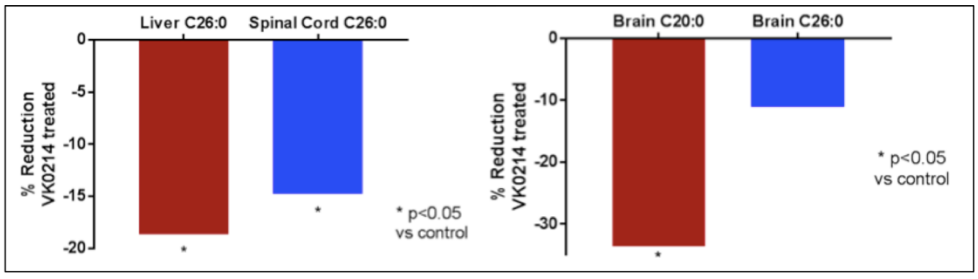
Source: Masamune *et al.*, 2017

Treatment with VK0214 resulted in a dramatic decrease in VLCFA levels in plasma only six weeks after initiating treatment, and this decline held relatively steady through the entire 25-week treatment period.



Source: Masamune *et al.*, 2017

Perhaps most importantly, tissue levels of VLCFAs were shown to be lower in mice treated with VK0214 compared to mice treated with vehicle control. The following figure shows there was a statistically significant decrease in the level of C26:0 in both the liver and spinal cord. In addition, in the brain there was a statistically significant decrease in C20:0 and an 11% decrease in C26:0 that trended toward significance (p=0.07).



Source: Masamune *et al.*, 2017

IND-enabling studies are currently ongoing for VK0214, and we anticipate an IND being submitted in the second quarter of 2020 and a Phase 1 proof-of-concept study being initiated shortly thereafter. The trial will likely involve a single-ascending dose study in healthy volunteers followed by a multiple ascending dose study also in healthy volunteers and then finally a multiple dose study in X-ALD patients. The company will be looking at 28-day dosing and will examine VLCFA levels before and after treatment. If those results are positive, the company would then meet with the FDA to discuss the regulatory path forward.

Financial Update

On February 26, 2020, Viking announced financial results for the fourth quarter and full year 2019. For the fourth quarter of 2019, the company had a net loss of $7.5 million, or $0.10 per share, compared to a net loss of $5.2 million, or $0.07 per share, in the fourth quarter of 2018. The net loss included $6.5 million in R&D expenses, compared to $5.1 million for the same period in 2018, with the increase primarily due to increased pre-clinical studies, manufacturing costs, consultants, and stock-based compensation. G&A expenses for the fourth quarter of 2019 were $2.4 million, compared to $1.9 million in the fourth quarter of 2018. The increase was primarily due to stock-based compensation, salaries, and legal expenses.

For 2019, Viking reported a net loss of $25.8 million, or $0.36 per share. R&D expenses were $23.6 million, compared to $19.0 million in 2018. The increase was primarily due to increased manufacturing costs, clinical costs, services provided by consultants, and salaries and benefits partially offset by a decrease in expenses for preclinical studies. G&A expenses in 2019 were $9.1 million, compared to $7.1 million in 2018. The increase was primarily due to stock-based compensation, professional services, and the use of consultants.

Viking exited 2019 with approximately $275.6 million in cash, cash equivalents, and short-term investments. We believe this is sufficient to fund operations at least through 2021. As of Jan. 31, 2020, Viking had approximately 72.6 million shares outstanding, and when factoring in stock options and warrants a fully diluted share count of approximately 81.8 million.

Conclusion

Outside of the EASL presentation in April 2020 and initiation of the VK0214 Phase 1 study, this year will likely be fairly quiet for Viking in terms of news flow as the company continues enrolling patients in the VOYAGE trial. In the meantime, we think investors should keep a close eye on the FDA's decision regarding Intercept Pharmaceuticals (ICPT) NDA for obeticholic acid (OCA) for the treatment of NASH. There will be an Advisory Committee (AdComm) meeting on April 22, 2020 and the PDUFA date is June 26, 2020. Two important points that will be very relevant for the NASH market as a whole that investors should pay attention to are: 1) will the FDA put a requirement for a biopsy in the label? (we view this as unlikely); and 2) will payers require a biopsy prior to authorizing treatment? (this could differ from one payer to the next). In addition, we anticipate data from a number of other companies developing NASH treatments, thus while Viking-specific news flow may be limited we believe there will be a lot of news flow for NASH in general in 2020. Our valuation for Viking remains at $24.

PROJECTED FINANCIALS

Viking Therapeutics, Inc.
Income Statement

Viking Therapeutics, Inc.	2019 A	Q1 E	Q2 E	Q3 E	Q4 E	2020 E	2021 E	2022 E
VK2809	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
VK0214	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Grants & Collaborative Revenue	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Cost of Sales	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-
Research & Development	$23.6	$7.0	$8.3	$9.5	$10.4	$35.2	$50.0	$60.0
General & Administrative	$9.1	$2.4	$2.4	$2.5	$2.5	$9.8	$10.5	$11.0
Other Expenses	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($32.7)	($9.4)	($10.7)	($12.0)	($12.9)	($45.0)	($60.5)	($71.0)
Operating Margin	-	-	-	-	-	-	-	-
Non-Operating Expenses (Net)	$6.9	$1.5	$1.4	$1.3	$1.3	$5.5	$5.0	$5.0
Pre-Tax Income	($25.8)	($7.9)	($9.3)	($10.7)	($11.6)	($39.5)	($55.5)	($66.0)
Income Taxes Paid	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	**($25.8)**	**($7.9)**	**($9.3)**	**($10.7)**	**($11.6)**	**($39.5)**	**($55.5)**	**($66.0)**
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.36)**	**($0.11)**	**($0.13)**	**($0.15)**	**($0.16)**	**($0.54)**	**($0.75)**	**($0.89)**
YOY Growth	-	-	-	-	-	-	-	-
Basic Shares Outstanding	72.0	72.5	72.7	72.9	73.0	72.8	74.0	74.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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