Zacks Small-Cap Research

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Durect Corporation

(DRRX-NASDAQ)

DRRX: Posidur FDA Meeting And Remoxy Update From Pfizer Expected Soon…

Current Recommendation	**Buy**
Prior Recommendation	Neutral
Date of Last Change	09/06/2012
Current Price (08/07/14)	$1.52
Target Price	**$3.00**

Update

We continue to be optimistic on the future of Durect Corp. We believe Remoxy remains the key driver of the stock, and with Pfizer currently running several Phase 1 studies in preparation of the NDA re-file in 2015. We note the remaining studies that Pfizer is running are expected to report data in the next few months. How much information Pfizer shares with investors remains to be seen, but we believe Durect shares may react favorably to an update from Pfizer on its third quarter 2014 conference call scheduled for late October 2014. Our NPV analysis pegs the valuation of Remoxy alone at $1.50 per share to DURECT. Other assets, including POSIDUR, ELADUR, Relday, and ALZET and LACTLE are worth another $1.00 to $1.50 per share based on probability-adjusted NPV analysis. As such, buying Durect at $1.52 per share seems like a low risk / potential high return investment.

SUMMARY DATA

52-Week High	**$2.22**
52-Week Low	**$1.04**
One-Year Return (%)	**20.64**
Beta	**1.20**
Average Daily Volume (sh)	**263,595**
Shares Outstanding (mil)	**111**
Market Capitalization ($mil)	**$168**
Short Interest Ratio (days)	**5.80**
Institutional Ownership (%)	**42**
Insider Ownership (%)	**11**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**14.7**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**

Risk Level	**High,**
Type of Stock	**Small-Growth**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	4.2 A	3.9 A	3.0 A	4.3 A	15.3 A
2014	6.3 A	4.6 A	3.8 E	4.3 E	19.0 E
2015					21.0 E
2016					26.0 E

Earnings per Share
(EPS is operating earnings before non recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.05 A	-$0.05 A	-$0.06 A	-$0.05 A	-$0.21 A
2014	-$0.03 A	-$0.05 A	-$0.05 E	-$0.06 E	-$0.19 E
2015					-$0.19 E
2016					-$0.14 E

Financial Results

On August 7, 2014, Durect Corp. (DRRX) reported financial results for the second quarter ending June 30, 2014. Total revenues in the quarter were $4.6 million, an increase of 17% over the second quarter 2013 and nicely above our forecast for revenues of $3.9 million. Revenues consisted of $2.8 million in sales of Alzet Pumps and Lactle Polymers. Revenues from these products have been fairly consistent over the past several quarters. Collaborative revenue came in at $1.7 million during the second quarter 2014, an increase of 92% year-over-year and nicely above our estimate for revenues of $1.0 million. During the second quarter of 2014, the company continued work on several feasibility projects and has multiple discussions underway with other parties about new feasibility projects utilizing the company's proprietary drug delivery technologies. Any one of these active R&D programs could turn into a product or technology licensing agreement, similar to what the company accomplished with Zogenix and Relday™ in June 2011.

Net loss for the second quarter totaled $5.4 million, or $0.05 per share. This was slightly better than expected on higher revenues and lower operating overhead. Durect exited the second quarter ending June 30, 2014 with approximately $33.0 million in cash and investments. The cash balance was strengthened during the quarter by a $20 million debt financing that took place in June 2014. The transaction was entered into with Oxford Finance LLC, pursuant to which Oxford agreed to make a term loan to Durect in the principal amount of $20 million. The loan has a fixed interest rate of 7.95% per annum with interest only payments for the first 18 months and repayment of all principal and interest by July 1, 2018. Durect had to pay a $150,000 facility fee at closing, and at maturity or earlier termination, the company must pay Oxford an additional one-time payment equal to 8% of the initial principal amount of the term loan (i.e. $1.6 million). Management plans to use the proceeds for general working capital and to fund operations. We see the current cash runaway extending into 2016.

Pfizer Still Working On Remoxy

In October 2013, Pfizer notified Pain Therapeutics and Durect that it had achieved technical milestones related to manufacturing of Remoxy®, and that they planned to continue move forward with development. Pfizer also noted, thanks to guidance received from the U.S. FDA that they planned to conduct several additional clinical studies with Remoxy prior to re-filing the NDA. Pfizer also noted that the FDA did not require further efficacy trials with Remoxy. Below is a snap-shot of Pfizer's activities with Remoxy. Note that some of these programs have been completed and some remain active:

Status	Study
Completed	Food Effect And Relative Bioavailability Study Of Oxycodone in Healthy Volunteers Condition: Healthy Intervention: Drug: Oxycodone
Completed	Single-Dose, Crossover Study To Compare Bioavailability Of Two Formulations Under Fed And Fasted Conditions Condition: Healthy Intervention: Drug: Oxycodone
Completed	Dose Proportionality Study Of PF-00345439 Formulation Under Fed Conditions Condition: Healthy Intervention: Drug: Oxycodone
Completed	Pharmacokinetics And Relative Bioavailability Study Of Oxycodone in Healthy Volunteers Condition: Healthy Intervention: Drug: Oxycodone

Status	Study
Recruiting	Abuse Potential Study of PF-00345439 Condition: Opioid Users Interventions: Drug: Capsule; Drug: PF-00345439; Drug: oxycodone
Recruiting	Effects of Food on Oxycodone Pharmacokinetics in Healthy Volunteers Condition: Healthy Intervention: Drug: Oxycodone
Recruiting	Effects of Ethanol on Oxycodone Pharmacokinetics in Healthy Volunteers Condition: Healthy Interventions: Drug: Oxycodone; Drug: Naltrexone

Source: ClinicalTrials.gov

We expect the three remaining active programs will wrap-up in the next few months. We were hoping that Pfizer would make a comment on its second quarter earnings call held on July 29, 2014, but we understand that Pfizer now will probably not say anything on Remoxy until all active programs have been completed. As such, we are hoping to hear something when Pfizer hosts its third quarter call in late October 2014.

As of their last update, Pfizer is still guiding to re-file the NDA around the middle of 2015. The rate-limiting step seems to be fulfilling the required twelve month stability under ICH guidelines for the new PF-00345439 "Formulation-K" product. Because the filing is a response to a FDA Complete Response Letter, the review period after the re-submission will be six months, meaning we could see a new Remoxy PDUFA late 2015.

We believe Remoxy has potential peak sales in the $1.5 billion range, and Durect's tiered royalty – roughly 9.1% at $1.5 billion in sales – would provide significant cash flow to the company. We model Remoxy approval in late 2015 at Pfizer, with sales eclipsing $1.5 billion by 2020. With a 15% discount rate on the cash flows, and 50% probability of approval, we see Remoxy alone worth $1.50 per share to Durect. This makes us comfortable with buying the stock at today's price. Investors are getting everything else for free.

FDA Meeting On POSIDUR CRL In September 2014

It has been six months since the February 2014 Complete Response Letter for POSIDUR™ (SABER®-Bupivacaine), the company's investigational post-surgical analgesic. The company has told investors that the CRL on POSIDUR is related to "imbalances" with respect to the safety data. We characterize the FDA's issues as a lack of safety data, not necessarily a specific issue with the safety of the drug itself. For example, when Durect conducted the clinical trials and analyzed the data for the NDA, efficacy data was compared to SABER-placebo. Based on management's comments, the FDA seemed to have no issues with POSIDUR's efficacy. The issue stems from a lack of safety data vs. an active comparator, such as bupivacaine HCl. In the simplest terms, the agency is comparing the efficacy of POSIDUR vs. placebo and safety vs. an active comparator.

Specifically, the company noted issues like somnolence, localized dryness and itching, and surgical site discolorations as these key imbalances. The FDA saw higher rates of these adverse events or side effects, but lacked sufficient data to quantify vs. an active comparator like bupivacaine HCl. For example, safety data from the 2010 European Phase 2b hysterectomy study noted post procedural hematomas at the surgical site. These were observed with frequency in the POSIDUR and SABER-Placebo groups and not observed in the active comparator group. Data from the 2012 Phase 3 BESST study showed a similar increase in local site reactions in the POSIDUR and SABER-Placebo groups when compared to the active comparator groups. The company noted that most of these observations were discolorations or localized dryness and itching, the majority of which resolved without treatment during the trial.

So it seems like to gain approval, Durect needs to conduct some head-to-head studies with POSIDUR vs. bupivacaine HCl and analyze the adverse events and side effects. Additionally efficacy data will also be collected in these trials. Management stopped short of predicting the nature of the trials, the numbers of patients, time, cost, and when they would be in position to re-file for approval. Before they publicly do that, Durect needs to meet face to face with the FDA. This meeting will take place in late September 2014.

Our guess, the company conducts two trials in hernia or cholecystectomy in 200-300 patients total, hopefully with both to start during the first half of 2015. Durect has noted being in partnership discussions on POSIDUR in the past. No doubt if the drug had been approved in February, management would have several interested parties making offers to commercialize the drug. The question remains whether or not any of these interested parties are willing to help fund these new studies or with the re-filing package. This is a difficult question to answer until Durect can meet with the U.S. FDA and qualify a path forward.

POSIDUR remains a meaningful opportunity in our view. There are roughly 70 million surgeries in the U.S. each year. There are approximately 1 million hernia procedures done in the U.S. each year. A 20% share in the U.S. hernia market at approximately $285 per procedure (priced at parity to Exparel®) represents a $57 million opportunity. Expanding into gallbladder, hysterectomy, shoulder surgery, etc… opens the door to a potential market of 10 to 20 million procedures that are ideally suited for a long-acting local analgesic like POSIDUR. Just 5% market share in this broader patient population represents at least a $250 million opportunity for Durect and a potential licensing partner. The market opportunity outside the U.S. is comparable. We believe POSIDUR, post-approval, could follow a similar path to Exparel and be generating $250 million in annual revenues three years after launch.

ELADUR Nearing Phase 3

In January 2014, Durect announced that it had granted an exclusive worldwide license to Impax Labs (IPXL) for the company's proprietary TRANSDUR transdermal delivery technology and other intellectual property to develop and commercialize ELADUR. ELADUR is an investigational transdermal bupivacaine patch for the treatment of pain associated with post-herpetic neuralgia (PHN), an indication for which the product has been granted Orphan Drug designation. Impax will assume control of ELADUR and fund the development and commercialization program, although the two companies will form a joint management committee to oversee and coordinate certain future research and development activities.

Under the terms of the transaction, Impax has agreed to pay Durect a $2.0 million upfront payment in cash. Durect is also eligible for up to $31.0 million in development and $30.0 million in commercialization milestones from Impax, along with a tiered mid single-digit to low double-digit royalty on annual net product sales determined on a country-by-country basis. Impax is planning to initiate a Phase 3 clinical study in the next several months. Initiation of this study nets Durect a small (undisclosed) milestone payment. The only thing we know about the size of the milestone payment is that it is greater than the $2.0 million upfront payment – so we include a $4.0 million payment from Impax to Durect in our financial model for the first quarter 2015. We believe ELADUR remains a meaningful opportunity for Impax and Durect, and thus are excited to see the Phase 3 trial begin.

Relday Chugging Along At Zogenix

In July 2011, DURECT and Zogenix, Inc. entered into a license agreement to develop and commercialize a proprietary, long-acting injectable formulation of risperidone using Durect's SABER controlled release formulation technology in combination with Zogenix's DosePro needle-free, subcutaneous drug delivery system. Durect received an upfront fee of $2.25 million, and can earn up to an additional $103 million in total future milestone payments, along with mid-single-digit to low double-digit royalty on annual net sales. Results from the Phase 1 study were released in January 2013. The next step is for Zogenix to conduct a multi-dose Phase 2b study. This is expected to initiate in the fourth quarter 2014 and offer data roughly nine months later.

ORADUR-ADHD & ORADUR-Opioids

In August 2009, Durect entered into a licensing and development agreement with Taiwan-based Orient Pharma Co., Ltd. Under terms of the agreement, Durect granted to Orient Pharma development and commercialization rights in certain defined Asian and South Pacific countries to an ADHD product that utilizes the ORADUR tamper-resistant technology; this is the same technology used in Remoxy. Durect retains rights to North America, Europe, Japan and all other countries not specifically licensed to Orient Pharma. The active drug candidate incorporated in the ORADUR formulation is methylphenidate (previously sold as branded Ritalin), the most widely used ADHD drug. The goal of the collaboration is to generate a clinical data package through a Phase 2 study, then partner in the U.S. If commercialized, Durect will be entitled to receive a royalty on sales of ORADUR-methylphenidate by Orient Pharma in its Asian territory.

Besides Remoxy (ORADUR-oxycodone), Pain Therapeutics (PTIE) controls the rights to three additional ORADUR-opioid formulations that utilized hydrocodone, hydromorphone and oxymorphone as the active drug. In Pain Therapeutics' fourth quarter recent press release, the company stated that it was looking at options to develop and commercialize these assets on its own or with a licensee of choice. We note that Investigational New Drug (IND) applications for all three drugs are in place with FDA. Durect is assisting Pain Therapeutics in getting ready to initial human clinical studies. For example, during the second quarter of 2014, Durect conducted R&D activities on these programs under approved workplans with Pain Therapeutics. Pain Therapeutics recently announced that they expect to start a Phase 1 clinical trial with ORADUR-Hydromorphone shortly, with an expectation of starting a Phase 3 trial for this product candidate in 2015.

We believe investors are placing little, if any value on the ORADUR pipeline. Perhaps this is based on the mishaps with Remoxy or the lack of active late-stage clinical programs. However, we note these programs can move rather quickly. If Pain Therapeutics moves into Phase 3 trials with ORADUR-Hydromorphone by the middle of 2015, we believe investors will start assigning meaningful value to the program. Coincidently, this is right around the time we are expecting Pfizer to re-file the NDA on Remoxy and the new Posidur Phase 3 trials to start reading-out. The second half of 2015 will be a very interesting and potentially rewarding time to be a Durect shareholder.

ALZET & LACTLE Providing Steady Cash Flow

DURECT currently manufactures and distributes ALZET miniature, implantable osmotic pumps and accessories used for experimental research in mice, rats and other laboratory animals. The company also designs, develops and manufactures a wide range of standard and custom biodegradable polymers based on lactide, glycolide and caprolactone under the LACTLE brand for pharmaceutical and medical device clients for use as raw materials in their products. Combined sales of ALZET and LACTLE products have been consistently growing over the past several years.

The chart below is taken from the company's historic filings and shows the growth in revenues from ALZET and LACTLE and the gross margin for the business. ALZET and LACTLE contribute revenues to the top-line and solid cash flow to help reduce operating burn. We see this business worth approximately $25 to $30 million in value based on 2.5x revenues.

	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Revenue	$6.9	$8.1	$8.3	$8.8	$9.1	$10.5	$10.6	$10.6	$11.4	$11.2
Gross Profit	$4.1	$4.9	$5.0	$5.4	$5.8	$6.6	$6.2	$5.9	$6.4	$6.4
Gross Margin	59%	60%	61%	62%	64%	63%	58%	56%	56%	57%

Source: DURECT Corp.

Conclusion

We continue to be optimistic on the future of Durect Corp. We believe Remoxy remains the key driver of the stock, and with Pfizer currently running a number of Phase 1 studies in preparation of the NDA re-file in 2015. We note that the remaining Phase 1 studies that Pfizer is running are expected to report data in the next few months. How much information Pfizer shares with investors remains to be seen. Nevertheless, we believe Durect shares may react favorably to an update from Pfizer on its third quarter 2014 conference call scheduled for late October 2014.

Our NPV analysis pegs the valuation of Remoxy alone at $1.50 per share to Durect. Other assets, including POSIDUR, ELADUR, Relday, and ALZET and LACTLE are worth another $1.00 to $1.50 per share based on probability-adjusted NPV analysis. Keep in mind, products like POSIDUR, ELADUR, Relday, and potentially even ORADUR-hydromorphone could all be in Phase 3 by the middle of 2015. The company also has $250 million in net operating losses (NOLs) to defer future taxes. As such, buying Durect Corp. at $1.52 per share seems like a low risk / potential high return investment.

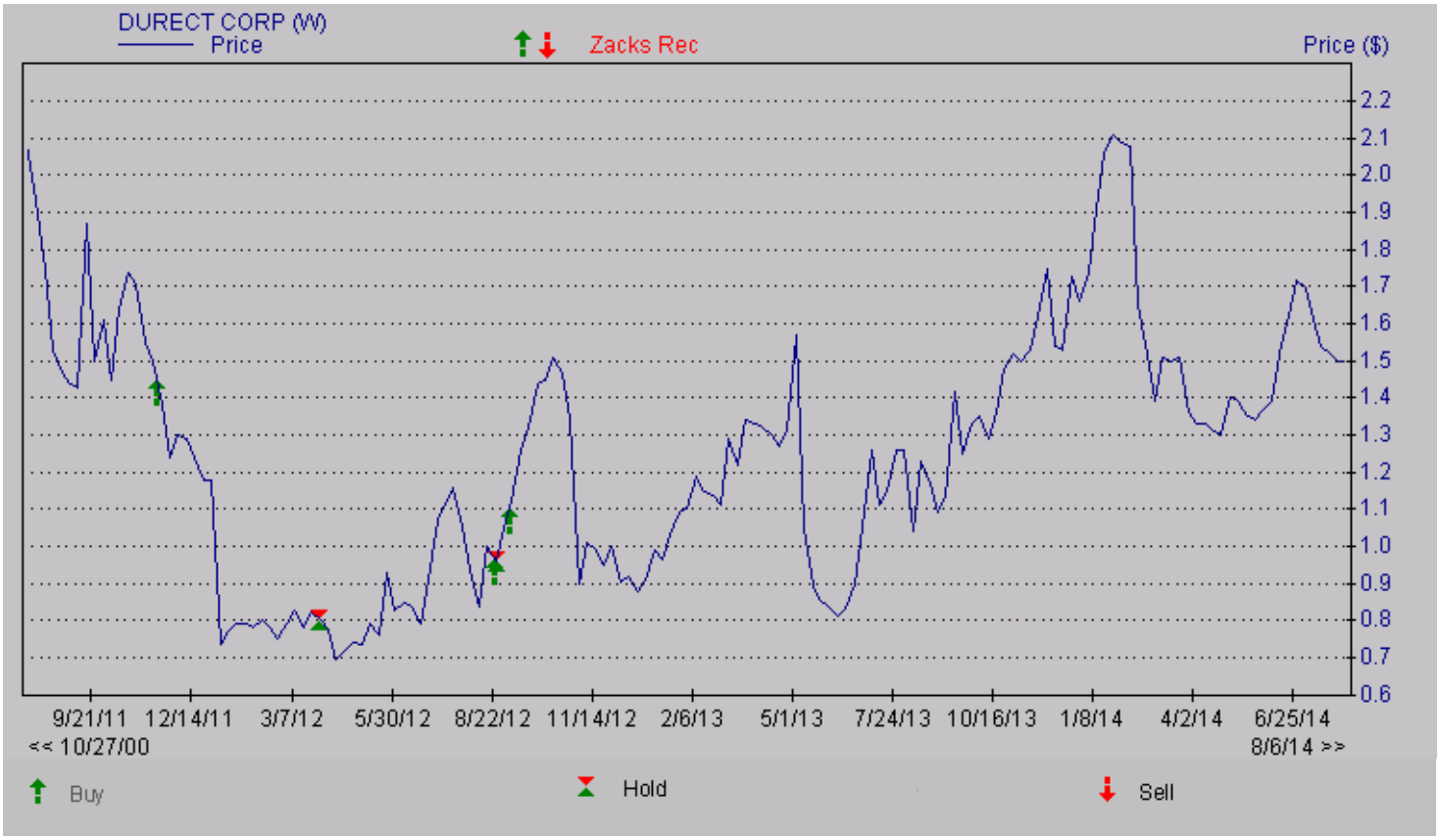
PROJECTED INCOME STATEMENT

Durect Corporation - Income Statement

DURECT Corp	2012 A	2013 A	Q1A	Q2A	Q3E	Q4E	2014 E	2015 E	2016 E
Posidur (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Remoxy (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0.0
YOY Growth	-	-	-	-	-	-	-	-	-
Sufentanil-Patch (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Eladur (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Relday (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
ORADUR-Opioids (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
ORADUR-Methylphenidate (Royalty)	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-
Alzet Pumps & Lactle Polymers	$10.6	$11.7	$2.8	$2.8	$2.8	$2.8	$11.2	$11.0	$11.0
YOY Growth	*-5.0%*	*11.0%*	*-14.2%*	*-5.5%*	*7.4%*	*-2.6%*	*-4.3%*	*-2.0%*	*0.0%*
Collaborative Revenue	$42.5	$3.6	$3.5	$1.7	$1.0	$1.5	$7.7	$10.0	$15.0
YOY Growth	*90%*	*-92%*	*285%*	*92%*	*179%*	*6%*	*116%*	*29.1%*	*50.0%*
Total Revenues	**$53.1**	**$15.3**	**$6.3**	**$4.6**	**$3.8**	**$4.3**	**$19.0**	**$21.0**	**$26.0**
YOY Growth	*58%*	*-71%*	*52%*	*17%*	*28%*	*0%*	*24%*	*10.7%*	*23.8%*
Cost of Goods Sold	$4.7	$4.8	$1.1	$1.1	$1.1	$1.1	$4.3	$4.2	$4.2
Product Gross Margin	*56.0%*	*58.8%*	*61.8%*	*61.7%*	*61.8%*	*61.8%*	*61.8%*	*62.0%*	*62.3%*
SG&A	$12.1	$12.7	$3.4	$2.9	$3.3	$3.4	$12.9	$13.5	$14.0
% SG&A	*22.8%*	*82.9%*	*53.4%*	*62.2%*	*86.8%*	*79.1%*	*68.1%*	*64.3%*	*53.8%*
R&D	$20.3	$18.9	$5.5	$6.1	$5.5	$6.0	$23.1	$25.0	$25.0
% R&D	*38.2%*	*123.6%*	*86.9%*	*132.9%*	*144.7%*	*139.5%*	*121.5%*	*119.0%*	*96.2%*
Operating Income	$16.1	($21.2)	($3.6)	($5.4)	($6.1)	($6.2)	($21.3)	($21.7)	($17.2)
Operating Margin	*30.3%*	-	-	-	-	-	*-112.2%*	*-103.2%*	*-66.0%*
Interest & Other Net	$0.1	($0.3)	$0.0	$0.0	$0.1	$0.1	$0.1	$0.1	$0.1
Pre-Tax Income	$16.2	($21.5)	($3.6)	($5.4)	($6.0)	($6.1)	($21.2)	($21.6)	($17.1)
Taxes	$0.0	$0.0	$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%*
Net Income	$16.2	($21.5)	($3.6)	($5.4)	($6.0)	($6.1)	($21.2)	($21.6)	($17.1)
YOY Growth	-	-	-	-	-	-	-	-	-
Net Margin	*30.5%*	-	-	-	-	-	*-111.5%*	*-102.8%*	*-65.6%*
Reported EPS	$0.18	($0.21)	($0.03)	($0.05)	($0.05)	($0.06)	($0.19)	($0.19)	($0.14)
YOY Growth	-	-	-	-	-	-	-	-	-
Shares Outstanding	88.6	103.1	110.5	110.6	110.7	110.8	110.6	115.0	120.0

Source: Zacks Investment Research, Inc. *Jason Napodano, CFA*

HISTORICAL ZACKS RECOMMENDATIONS



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Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

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