Zacks Small-Cap Research

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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Vastly Under-valued, and SYNERGY Data In Q3-2012 Could Be The Catalyst…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	09/13/2010
Current Price (05/03/12)	$1.04
Target Price	**$3.00**

UPDATE

Zalicus has been making significant progress over the past few months in bringing new candidates into the clinic. In December 2011, management initiated phase 1 trials on both Z160, a novel oral N-type calcium channel blocker, and Z944, a novel oral T-type calcium channel blocker. Z160 has successfully completed its trial and we are expecting news on Z944 in a few months. In the meantime, the phase 2b SYNERGY trial continues on plan with data expected in the third quarter 2012.

We rate the shares 'Outperform' and have a price target of $3 per share.

SUMMARY DATA

52-Week High	**$2.89**
52-Week Low	**$0.84**
One-Year Return (%)	**-58.53**
Beta	**2.16**
Average Daily Volume (sh)	**793,278**
Shares Outstanding (mil)	**105**
Market Capitalization ($mil)	**$112**
Short Interest Ratio (days)	**1.17**
Institutional Ownership (%)	**26**
Insider Ownership (%)	**2**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Blend**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	1.3 A	1.8 A	2.4 A	2.6 A	8.2 A
2012	2.3 A	2.6 E	2.9 E	3.4 E	11.2 E
2013					18.0 E
2014					11.1 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.12 A	-$0.11 A	-$0.09 A	-$0.11 A	-$0.43 A
2012	-$0.13 A	-$0.11 E	-$0.12 E	-$0.12 E	-$0.47 E
2013					-$0.29 E
2014					-$0.30 E

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WHAT'S NEW

Financial Results

On May 3, 2012, Zalicus reported financial results for the first quarter 2012. Total revenues in the quarter were $2.3 million. Revenues consisted of $1.2 million in collaborative payments and $1.1 million in royalties on sales of Exalgo at partner Covidien. Exalgo royalties were up 33% from the fourth quarter 2011.

Net loss for the first quarter 2012 was $13.5 million, or $0.13 per share. This was in-line with our estimate for net loss of $0.13 per share. Net loss was driven by $10.6 million in SG&A, $2.7 million R&D, and $2.1 million in amortization and restructuring. Zalicus exited the first quarter ended March 31, 2012 with $52.5 million in cash, investments, and restricted cash. We remind investors that on March 28, 2012, Zalicus filed an 8K noting that it has completed its planned equity distribution agreement with Wedbush Securities. Since enacting the "ATM" in January 2012, Zalicus sold a total of 14.058 million shares into the public market to raise gross proceeds of $15.0 million. We find the current cash balance to be sufficient to fund operations into the middle of 2013.

INVESTMENT THESIS

We are expecting Zalicus to offer-up a steady flow of news over the next several months, with the key event being the release of top-line data from the phase 2b SYNERGY trial expected in the third quarter 2012.

Top-Line Data From Phase 2b SYNERGY Expected Q3-2012

In June 2011, Zalicus announced it had initiated a phase 2b clinical trial evaluating Synavive for the treatment of rheumatoid arthritis (RA). The trial, SYNERGY (SYNavivE for Reducing signs and sYmptoms of rheumatoid arthritis trial), is a 12-week, 5-arm, double-blind, placebo-controlled study to evaluate the safety and efficacy of Synavive as a treatment for the signs and symptoms of rheumatoid arthritis (RA) in approximately 250 subjects with moderate to severe disease. On April 30, 2012, the company announced enrollment has been completed and top-line data is expected in the third quarter 2012. Full data should be available later in 2012. If timelines hold, management should be able to sit down with the FDA for a post-phase 2 meeting early 2013.

…About SYNERGY…

The trial was conducted in up to 60 centers throughout the U.S., Europe, and Latin America. Enrollment should be evenly split between the three regions. The primary endpoint is efficacy measured by the Disease Activity Score in 28 Joints (DAS28). DAS28 is a common, patient specific, outcome tool used in therapeutic trials to assess disease improvement or response. Key secondary objectives include evaluating the efficacy of Synavive compared to its individual components (2.7mg of prednisolone and 360mg of dipyramidamole) as well as how Synavive performs in comparison to 5mg of prednisolone. We expect the typical patient will have moderate-to-severe RA, over the age of 60, currently on stable doses of methotrexate (MTX) but not yet progressed to biologics.

Subjects who complete the core SYNERGY trial (or at least 6 weeks on drug) will be eligible to participate in a one-year extension study designed to investigate the long-term safety and durability of response for Synavive. Key safety and tolerability issues will be weight gain and glucose levels, along with cataract formations or changes in visual acuity. Besides demonstrating efficacy on par with the 5mg prednisolone cohort, we believe it is paramount that Synavive demonstrate meaningful improvements in overall tolerability vs. 5mg prednisolone and 360mg dipyridamole (immediate release).

DAS28	placebo	dipyridamole (360mg)	prednisolone (2.7mg)	Synavive (2.7/360mg)	prednisolone (5mg)
Baseline					
Change at Week-12					
p-value					
	NEGATIVE CONTROLS		*TEST SUBJECTS*		

Ion Channel Pipeline Rolling Forward

Beyond Synavive, Zalicus is developing an attractive suite of ion channel candidates for both acute and chronic pain. These include T-type and N-type calcium channel blockers and Nav1.7 sodium channel blockers. In early February 2012, Zalicus and Hydra Biosciences, Inc., a leader in the discovery and development of novel ion channels, announced that they have entered into a collaboration to advance development of Zalicus' preclinical ion channel modulator product candidates for the treatment of pain. We like the deal from a cost-savings and development standpoint. This collaboration brings together the Zalicus portfolio of novel, preclinical ion channel product candidates, representing multiple calcium and sodium channel modulators, with Hydra's expertise in ion channel discovery and preclinical drug development. The goal of the collaboration is to advance ion channel drug candidates into clinical development for the treatment of pain. The collaboration does not include Z160 or Z944, already in human clinical trials.

Under the terms of the agreement, Zalicus paid Hydra an upfront payment (undisclosed) and will fund research and development activities at Hydra for a two-year period. Hydra will perform the preclinical development activities necessary and Zalicus will retain all intellectual property and commercial rights to its product candidates. In connection with the collaboration agreement, Zalicus also announced it closed its Vancouver, British Columbia-based ion channel discovery research operations, resulting in a workforce reduction of 16 employees (approximately 28% of the workforce).

We note that Zalicus recorded a $1.1 million restructuring charge in the first quarter 2012 financials. However, the costs savings from closing down Vancouver, the old Neuromed headquarters, should be in the area of $3 to $4 million for 2012 alone. The upfront payment to Hydra was undisclosed, but we are modeling the deal to be cash neutral in 2012. In 2013, Zalicus will continue to fund preclinical activities at Hydra, but the costs will be more variable as opposed to fixed costs associated with owning the Vancouver facility. If Zalicus is having success, they will spend more. If things aren't going so well they can pull back.

…Z160 Successfully Completes Phase 1…

On March 5, 2012, Zalicus announced it had successfully completed a phase 1 (n=16) pharmacokinetic and safety study with new formulations of Z160 (formerly MK6721), a novel oral N-type calcium channel blocker (Cav2.2). Management noted that Z160 has been reformulated to overcome bioavailability and food effect challenges from previous studies. One formulation demonstrated a 6-fold increase in bioavailability based on the PK/PD analysis from the phase 1 program.

We remind investors that Merck paid Neuromed $25 million upfront to license MK6721 (then called NMED160) back when the molecules was still in preclinical testing. The agreement between Merck and Neuromed called for an additional $450 million in potential development and commercialization milestones and royalties on sales. Unfortunately, the poor bioavailability of NMED160 resulted in Merck walking-away from the collaboration following a disappointing phase 1 trial in August 2007. If Zalicus has reformulated Z160 to where the bioavailability is now attractive, we see no reason why the company could not command a deal with big pharma following proof-of-concept (phase 2a) data in 2013.

Zalicus should be in position to commence a phase 2a trial in neuropathic pain during the third quarter of 2012. We remind investors that preclinical data suggests Z160 is effective across multiple models of inflammation and neuropathic pain. Possible indications include post-herpetic neuralgia (PHN), diabetic peripheral neuropathy (DPN), fibromyalgia, chronic lower-back pain, peripheral nerve pain, etc… We believe the new formulations being developed by Zalicus may also improve patent protection. We think management's goal will be to show utility in two of these potential indications, and then look to sign a development and commercialization partnership for Z160.

…Z944 To Complete Phase 1 Soon…

On December 19, 2011, Zalicus announced the initiation of a phase 1 clinical trial evaluating the pharmacokinetics and safety of Z944, a novel oral T-type calcium channel blocker with demonstrated preclinical potential for the treatment of acute and inflammatory pain in animal pain models. The phase 1 trial is taking place in the United Kingdom. We are expecting results from the trial to be announced in the third quarter 2012. This is a maximum-tolerated-dose (MTD) program, so conceivably, the longer it runs the better. Based on previous phase 2a programs in pain / inflammation, this study can move rather quickly (at low cost), which would put Zalicus in position to seek out-licensing partners for Z944 in 2013.

T-type calcium channels have been recognized as key targets in the therapeutic inhibition of a broad range of cell functions and have been implicated in the frequency and intensity of pain signals. During the first quarter, Zalicus published preclinical data in the journal Science Translational Medicine, describing the activity of Z944 to potently suppress seizures. This data reinforces the potential biologic activity of Z944, as it is generally understood that conditions of neuronal hyper-excitability, such as epilepsy and pain, are mechanistically linked. If Z944 is safe and well tolerated, Zalicus is planning to advance it into phase 2a clinical trial in 2013.

…Out-Licensing To Come…

Between the above two candidates and the preclinical pipeline now being developed at Hydra, we believe Zalicus has the potential to sign ion channel development partnership in 2013 and 2014. We find it interesting that in January 2012, Roche announced a collaboration agreement with privately-held Xenon Pharmaceuticals to discover and develop compounds for the treatment of pain. Under terms of the agreement, Xenon could earn up to $646 million in research, development, and commercialization related milestones plus royalties from Roche. Xenon's most advanced candidate, XEN402, is an oral Nav1.7 inhibitor currently in phase 2 clinical trials. This could provide a good valuation road-map for Zalicus in 2013 when it seeks to partner or out-licenses its phase 2 candidates.

Prednisporin Still Alive At Sanofi

Sanofi continues its formulation scale-up work on Prednisporin. We remind investors that Sanofi initiated a phase 2b clinical program testing Prednisporin in subjects with persistent allergic conjunctivitis in June 2010. This trial has completed in December 2010, but Sanofi has not shared the results. However, the fact that Sanofi has moved into scale-up for a commercial formulation is a clear sign that the data was positive. We are expecting Sanofi to conduct a bridging study with this new formulation later this year, and then move into a phase 3 program sometime during the second half of 2012.

Zalicus is eligible for $3 million milestone payment from Sanofi when the phase 3 trial initiates. If commercialized, Zalicus is eligible to receive milestone payments of up to approximately $65 million and tiered royalty payments of up to 12% on the development and commercialization of certain products generated from the Zalicus platform. The milestone $65 million schedule includes: $25 million in development and regulatory milestones, $25 million in sales-related milestones, and $15 million in additional indication approval milestones. We note prednisporin may have potential for the treatment of dry eyes as well.

Exalgo Royalties Up Nicely In Q1

Exalgo royalties during the first quarter 2012 totaled $1.1 million, up 33% sequentially from the fourth quarter 2011. Covidien has been very tight lipped about the status of the 32mg dose tablet with Exalgo – perhaps trying to keep generic companies in the dark. As noted in our previous reports, the 32mg dose of Exalgo will make the product more competitive with Endo's Opana-ER. We note that gaining approval of a 32mg dose for Exalgo will also extend the intellectual property protection for Covidien, as Watson has not challenged the 32mg dose (as of yet).

In December 2011, Covidien announced it would spin-out its pharmaceutical division to shareholders. We think this is good news for Zalicus, as the new stand-alone pharmaceutical company will be seeking to expand its top-line and provide growth through new products. We think driving Exalgo growth with a 32mg tablet will be key to this goal for the new pharma division once independent.

Novartis Collaboration Renewed

In May 2009, Zalicus entered into a strategic alliance and research collaboration with Novartis for the discovery of novel anti-cancer combinations. Under the agreement, each party will contribute compounds and evaluate the anti-cancer effects by utilizing Zalicus' proprietary cHTS platform and Chalice analyzer software to screen a unique library of molecules, including Novartis compounds in multiple cell lines representing a broad spectrum of cancers. Zalicus received an upfront payment of $4 million, plus $3 million per year for two years in research support funding. The company is also eligible to receive up to $58 million in clinical, regulatory and commercial milestones for each combination that is commercialized under the collaboration. In April 2012, Zalicus announced that Novartis has exercised its second option to extend its oncology discovery research collaboration with Zalicus for an additional contract year, through April 2013.

Much like the company's preclinical ion channel platform, we think that Zalicus' preclinical discovery in oncology is vastly under-valued by investors. The company has been active in publishing papers over the past few months, aiming to increase investor attention and awareness of the oncology discovery platform.

- ✓ Published preclinical data in the journal Molecular Cancer Therapeutics, in which Zalicus researchers, in collaboration with the Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute, Harvard Medical School, have discovered that adenosine A2A and beta-2 adrenergic receptor agonists are highly synergistic and selective novel agents that enhance glucocorticoid activity in B-cell malignancies such as multiple myeloma and, importantly, can synergize in combination with current multiple myeloma treatment regimens such as melphalan, lenalidomide, bortezomib and doxorubicin.

- ✓ Published an editorial in a special Targeted Oncology issue of the journal Future Medicinal Chemistry in which Dr. Lee discusses the promise and progress to date of the biopharmaceutical industry to adopt a systematic, high-throughput approach to identify selective and synergistic cancer combination therapies to provide meaningful clinical benefit to cancer patients.

- ✓ Presented on the systematic discovery of novel cancer combination targets and therapeutics at the 3rd annual Cancer Targets and Therapeutics conference in Las Vegas, February 27-28, 2012.

RECOMMENDATION

We are maintaining our Outperform rating, and $3.00 price target on shares of Zalicus. The biggest driver of the stock in 2012 will be the results of the SYNERGY trial in the third quarter 2012. Besides this however, we see several potential catalysts that could drive the shares higher:

- ✓ Reporting phase 1 data on Z944 in the third quarter 2012.
- ✓ Initiating a phase 2a program with Z160 in the third quarter 2012.
- ✓ Reporting phase 2b data on SYNERGY during the third quarter 2012.
- ✓ Initiating a phase 2a program with Z944 in the fourth quarter 2012.
- ✓ Forming additional cHTS or ion channel collaborations during the second half of 2012.
- ✓ Sanofi initiating a phase 3 trial on Prednisporin during the second half of 2012.
- ✓ Covidien receiving approval for the 32mg Exalgo dose during the second half of 2012.
- ✓ Partnering Synavive for phase 3 trials in 2013.
- ✓ Partnering Z160 for phase 2b trials in 2013.
- ✓ Partnering Z944 for phase 2b trials in 2013.
- ✓ Moving additional ion channel candidates into the clinic in 2013.

PROJECTED INCOME STATEMENT

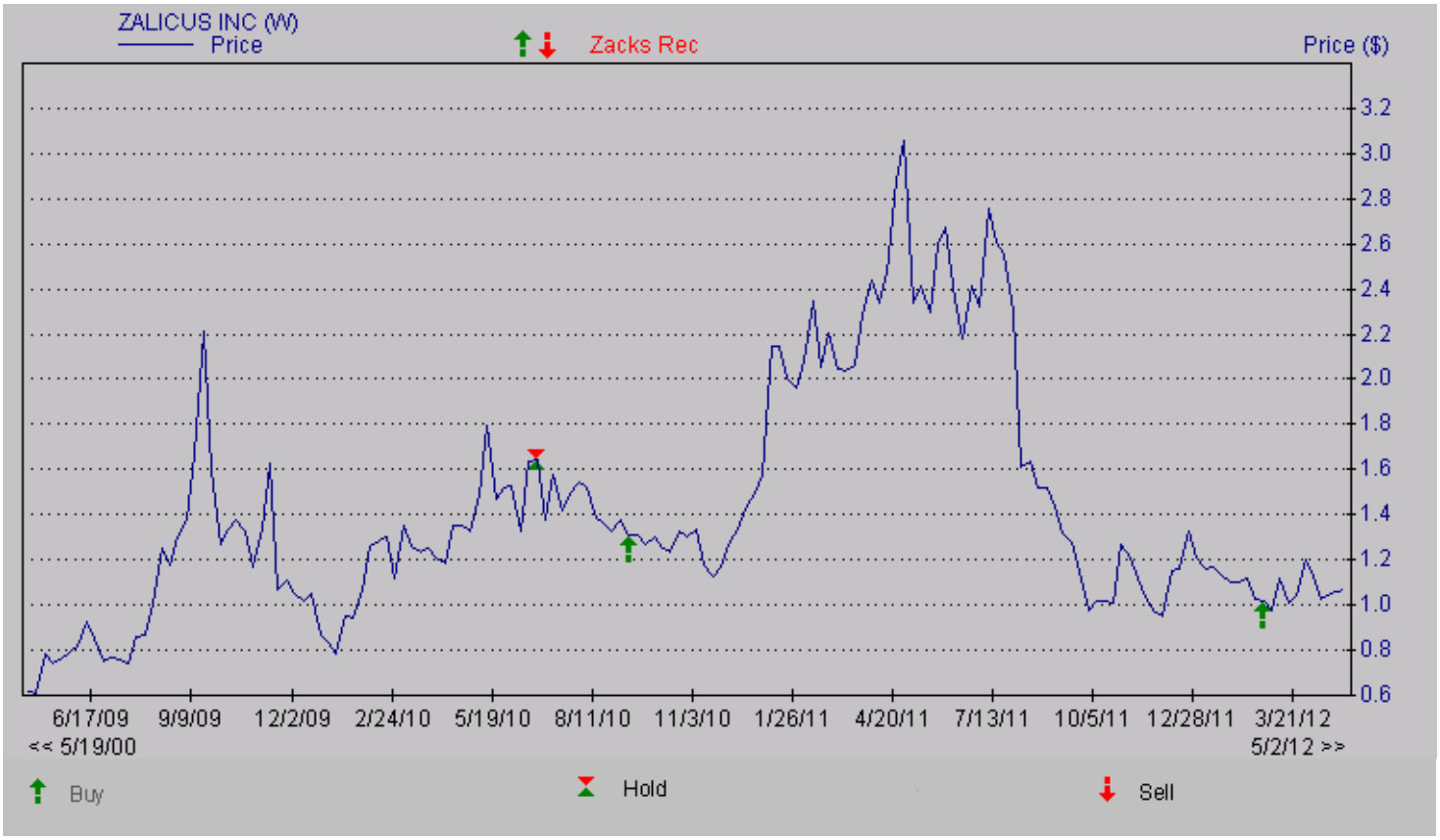
Zalicus, Inc.
Income Statement

Zalicus, Inc.	2010 A	2011 A	Q1 A	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E	2015 E
Collaborations & Grants	**$45.2**	**$5.7**	**$1.2**	**$1.4**	**$1.5**	**$1.6**	**$5.7**	**$7.5**	**$10.0**	**$15.0**
YOY Growth	*161.4%*	*-87.3%*	*32.5%*	*3.9%*	*-7.9%*	*-12.9%*	*-0.2%*	*31.1%*	*33.3%*	*50.0%*
Exalgo Royalty	**$1.6**	**$2.5**	**$1.1**	**$1.2**	**$1.4**	**$1.8**	**$5.5**	**$10.5**	**$1.1**	**$0.8**
YOY Growth	-	*54.2%*	*214.3%*	*140.0%*	*75.0%*	*125.0%*	*124.5%*	*90.9%*	*-89.7%*	*-24.3%*
Synavive	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Prednisporin	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Z160	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Z944	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Total Revenues	**$46.7**	**$8.2**	**$2.3**	**$2.6**	**$2.9**	**$3.4**	**$11.2**	**$18.0**	**$11.1**	**$15.8**
YOY Growth	*170.6%*	*-82.5%*	*82.5%*	*40.7%*	*19.4%*	*28.9%*	*37.1%*	*60.4%*	*-38.4%*	*42.8%*
General & Administrative	$12.1	$10.4	$2.7	$2.5	$2.4	$2.5	$10.1	$10.5	$11.0	$12.0
% SG&A	*25.9%*	*127.1%*	*114.8%*	*96.2%*	*82.8%*	*73.5%*	*89.7%*	*58.3%*	*99.3%*	*75.9%*
Research & Development	$23.0	$35.3	$10.6	$10.0	$11.5	$12.5	$44.6	$35.0	$30.0	$30.0
% R&D	*49.2%*	*431.3%*	*456.1%*	*384.6%*	*396.6%*	*367.6%*	*397.3%*	*194.4%*	*270.7%*	*189.6%*
Amort & Restruct	$18.7	$5.1	$2.1	$1.3	$1.2	$1.2	$5.8	$4.5	$4.0	$4.0
% Other	*40.1%*	*62.8%*	*89.4%*	*50.0%*	*41.4%*	*35.3%*	*51.5%*	*25.0%*	*36.1%*	*25.3%*
Operating Income	($7.1)	($42.7)	($13.0)	($11.2)	($12.2)	($12.8)	($49.2)	($32.0)	($33.9)	($30.2)
Operating Margin	-	-	-	-	-	-	-	-	-	-
Interest & Other Net	($29.2)	($0.8)	($0.5)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)
Pre-Tax Income	($36.3)	($43.5)	($13.5)	($11.4)	($12.4)	($13.0)	($49.4)	($32.2)	($34.1)	($30.4)
Taxes	($1.2)	($1.2)	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Discontinued Operations	$0	$0.0	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	($35.0)	($42.3)	($13.5)	($11.4)	($12.4)	($13.0)	($49.4)	($32.2)	($34.1)	($30.4)
YOY Growth	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-
Reported EPS	**($0.42)**	**($0.43)**	**($0.13)**	**($0.11)**	**($0.12)**	**($0.12)**	**($0.47)**	**($0.29)**	**($0.30)**	**($0.26)**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares	82.6	97.3	103.8	104.0	106.0	108.0	105.4	110.0	115.0	115.0

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

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