Zacks Small-Cap Research

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Zalicus Inc.

(ZLCS-NASDAQ)

ZLCS: Phase 2b Synavive To Start Soon, Ion Channel Candidates Offer Upside.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	09/13/2010
Current Price (03/09/11)	$2.09
Target Price	**$3.00**

UPDATE

We use a Sum-Of-Parts valuation methodology to determine fair-value for Zalicus. Out work shows the company is under-valued at the current stock price. We see a market capitalization of $260 million, or $3 per share, as more fairly valuing the company's core assets, which include royalties from Exalgo, phase 2b candidate Synavive, and a growing early-stage pipeline through in-house and external research collaborations. We see upside to this figure based on positive developments or updates on prednisporin at Sanofi, Exalgo, or the ion channel partnering efforts.

We rate the shares 'Outperform'.

SUMMARY DATA

52-Week High	**$2.65**
52-Week Low	**$1.06**
One-Year Return (%)	**69.05**
Beta	**1.71**
Average Daily Volume (sh)	**1,533,197**
Shares Outstanding (mil)	**89**
Market Capitalization ($mil)	**$190**
Short Interest Ratio (days)	**1.08**
Institutional Ownership (%)	**14**
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 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**1**

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)
2010	41.3 A	2.9 A	1.2 A	1.3 A	46.7 A
2011	1.5 E	4.6 E	2.0 E	3.3 E	11.4 E
2012					20.5 E
2013					33.8 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.05 A	-$0.10 A	-$0.13 A	-$0.13 A	-$0.42 A
2011	-$0.13 E	-$0.10 E	-$0.14 E	-$0.13 E	-$0.50 E
2012					-$0.39 E
2013					-$0.22 E

Zacks Projected EPS Growth Rate - Next 5 Years % N/A

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WHAT'S NEW

Recent Financials

On March 9, 2011, Zalicus reported financial results for the fourth quarter and full year 2010. Total revenues in the fourth quarter were $1.3 million, of which $0.4 million was royalties on sales of Exalgo at Covidien. This was in-line with our expectations. For the full year 2010, revenues totaled $46.7 million, $1.6 million of which was royalties on Exalgo and $40.0 million of which was a milestone payment from Covidien on Exalgo approval in the first quarter 2010. The remaining revenues during the year included collaborations and research grants.

Net loss for the fourth quarter totaled $12.0 million, or $0.13 per diluted share. This was in-line with expectations. For the full year 2010, net loss totaled $35.0 million, or $0.42 per diluted share. Zalicus exited 2010 with $46.5 million in cash and investments. We view this to be sufficient cash to fund operations into 2013. We note that on December 22, 2010, Zalicus entered into a loan and security agreement with Oxford Finance Corporation for up to $20 million. The loan included three terms: Term-A: $3.0 million upfront, Term-B: $8.5 million on or before July 15, 2011, and Term-C: $8.5 million on or before January 15, 2012. As of now, management has only taken down the initial $3.0 million upfront payment. Zalicus also has a $20 million equity distribution agreement with Wedbush Securities relating to shares of common stock.

INVESTMENT OVERVIEW

Exalgo

Since the launch in late April 2010, Covidien continues to provide tidbits of information on the Exalgo, most recently noting in January 2011 that the launch is on plan with peak sales on track for $250 to $300 million. We remind investors that Covidien is responsible for all commercialization activities for Exalgo in the U.S., including marketing and sales, and for all post-approval regulatory activities. Covidien launched the product with roughly 275 sales representatives and a dozen region directors.

Zalicus is receiving a tiered royalty on net sales of Exalgo by Covidien. Cumulative royalties since the launch has totaled $1.6 million. Royalties in the fourth quarter 2010 were $0.4 million. We are beginning to see end-user demand work through the initial wholesaler launch stocking. We are expecting demand to begin tracking with prescriptions over the next few months. We expect Zalicus to see a sizable ramp in royalties in the second quarter 2011.

Exalgo is an extended release hydromorphone indicated for the treatment of moderate-to-severe pain in opioid tolerant patients requiring continuous (around the clock) analgesia. The product is the only extended-release hydromorphone treatment available in the U.S. The product provides opioid-tolerant patients suffering from moderate-to-severe chronic pain, relief for 24 hours per dose with significant improvement over traditional immediate release hydromorphone products. The concept of controlled-release opioids has been well defined in the market. The long-acting opioid (LAO) market in 2009 tallied nearly 25 million prescriptions and $6 billion in sales.

Exalgo is currently on the market in Europe as Jurnista, sold by J&J subsidiary, Janssen-Cilag. Since 2006, Jurnista has captured roughly 4% prescription share and 6% dollar share of the long-acting opioid market in Germany. In the U.S., short-acting hydromorphone products accounted for 3 million prescriptions in 2009. Capturing share of the immediate-release hydromorphone market could equate to a $250 to $300 million opportunity for Exalgo. For example, Endo Pharma's Opana ER, an extended release oxymorphone HCl, has an estimated 3% prescription share (5% dollar share) of the LAO market, and posted global sales of $231 million in 2009. Covidien has identified approximately 12,000 high volume hydromorphone prescribers to target for the first-wave of the commercial launch. These 5% of total prescribing physicians account for roughly 50% of the total LAO market. Covidien's goal is to reach the majority of these 12,000 by year end 2011.

Synavive

Following consultation with the U.S. FDA, Zalicus has mapped out the next step in development for Synavive. Management plans to initiate a phase 2b program in rheumatoid arthritis (RA) in the second quarter of 2011. We note that prior to selecting RA, Zalicus conducted a series of interviews with key opinion leaders, practicing rheumatologists, primary care doctors and managed care personnel to fully explore the potential benefits of moving into RA as an initial indication for Synavive. Based on their feedback, management believes that RA is the most attractive choice on a number of fronts including current medical practice in which there is already a high prevalence of glucocorticoid use in RA to combat inflammation and restore function, as well as the unmet need for less expensive, easier to access options to biologic therapy.

The phase 2b trial, to be called SYNERGY (Synavive for Reducing Signs and Symptoms of Rheumatoid Arthritis) trial, is a twelve-week double-blind, placebo-control program that is expected to enroll up to 250 patients with moderate to severe rheumatoid arthritis in 5-Arms at 60 centers around the U.S., Europe, South / Central America. The primary endpoint will be efficacy measured by the Disease Activity Score in 28 Joints (DAS28). DAS28 is a common outcome tool used in therapeutic trials to assess disease improvement or response. Management will also conduct a one-year extension study to assess the long-term safety and durability of response for Synavive. We estimate the program will take approximately 12 months to complete, thus we are expecting top-line data in the third quarter of 2012.

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

The trial is set up to demonstrate that Synavive, a combination of 360mg dipyridamole and 2.7mg prednisolone, will show superiority to placebo and the individual components, and offer non-inferiority to the higher dose of 5mg prednisolone. In the future we expect Zalicus will compare Synavive to even higher doses of prednisolone. The ultimate goal of Synavive would be to replicate a 7.5mg dose of prednisolone, albeit without the side-effects commonly associated with high doses of corticosteroids. This would allow RA patients to take Synavive daily as a maintenance therapy to prevent flare-ups.

RA patients typically start treatment with methotrexate (MTX) and move to corticosteroids / glucocorticoids such as prednisolone to control flare-ups. Patients also often use NSAIDs or Cox-II inhibitors to control pain. The most severe flare-ups are treated with biologics. Rheumatologists do not like to prescribe high doses of prednisolone as a maintenance therapy to control flare-ups due to the potential for serious side-effects such as high blood sugar, dyslipidemia, weight gain, insomnia, and weakening immune system.

The ability to safely control RA patients through Synavive could be a meaningful opportunity. The treatment paradigm for osteoarthritis (OA) plays out in a similar fashion. In the U.S. more than 100 million people suffer from RA and OA combined. We encourage investors to view our research report from November 2010 that discusses the previous phase 2 data with Synavive in the phase 2a RA program and the phase 2b COMET-1 OA program. Beyond RA and OA, we believe Synavive has potential in other steroid-responsive diseases such as polymyalgia rheumatica (PMR), lupus (SLE) and ulcerative colitis (Crohn's).

Recently, the Synavive composition-of-matter patent has been allowed by the U.S. patent and trademark office and is expected to be issued within the coming months. This patent, along with the existing issued method of use patent, should protect Synavive exclusivity until 2028.

Prednisporin

In June 2010, Sanofi initiated a phase 2b clinical program testing prednisporin in subjects with persistent allergic conjunctivitis. Zalicus received a $500,000 milestone payment from Fovea relating to this initiation. The trial completed in December 2010, although Sanofi has yet to report the results of the program. Looking back at the history of Sanofi's disclosure and phase 2 candidates, we are not expecting management to make the results public prior to the initiation of a phase 3 program.

The best we can do at this point with prednisporin is wait around for Sanofi to announce they are moving forward into phase 3 as a sign the trial was positive. As a reminder, this will result in a $3 million milestone payment from Sanofi to Zalicus. 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.

Ion Channel Programs

Zalicus has selected its first ion-channel candidate to move forward into advanced IND-enabling toxicology studies prior to the initiation of a phase 1 program planned for later this year. The candidate, Z944 is a novel T-type calcium channel blocker. Preclinical data from inflammatory pain models suggests the candidate has excellent efficacy. Management plans to be in position to file the IND during the second quarter of 2011. This would allow for the initiation of a phase 1 program over the summer, with a larger-scale phase 2a program to start before the end of the year. Based on what we have seen with 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 2012.

Zalicus also plans to move Z160 (formerly NMED-160), a novel oral N-type calcium channel blocker, into phase 1 trials by the end of the year. Z160 has been reformulated to address previous solubility and bioavailability issues that stalled the candidate despite promising early-stage data in over 200 subjects to date.

We note that management has several additional preclinical ion channel candidates following behind Z944. These include other T-type and N-type calcium channel blockers and Na1.7 sodium channel blockers. In fact, Zalicus published a paper on the preclinical data from Z212 in the Journal of Pain in February 2011. The paper describes the activity of Z212, a novel proprietary small organic compound that acts to modulate Nav1.7 and Nav1.8 sodium channels and to reduce neuropathic pain by targeting the hyper-excitability associated with chronic pain signaling pathways. Through its unique mechanism of action, Z212 has been shown to both reduce the excitability of neurons and reverse pain hypersensitivity in preclinical models. We are expecting an IND on Z212 later in 2011 or in 2012.

Between the above three candidates we believe Zalicus has the potential to sign either one broad-scale Ion Channel development partnership in 2011, or three separate smaller deals. It really comes down to each products differentiation and how much of a commitment a larger organization is seeking to make in ion channel. We expect that Zalicus will look to complete phase 1 trials on each of the above candidates before individually out-licensing. A broad scale platform collaboration, however, could come sooner.

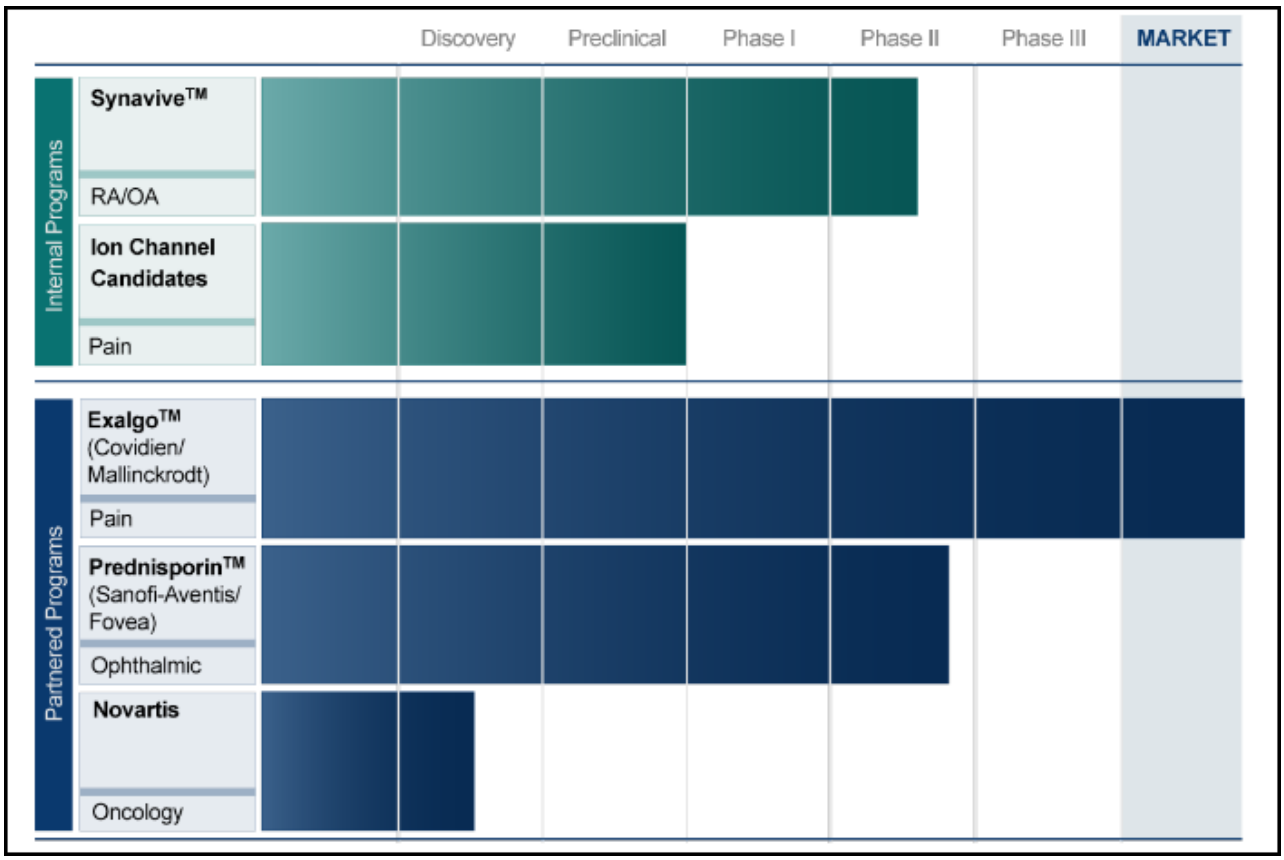
Novartis

Novartis recently notified Zalicus that it will extend its strategic alliance and research collaboration for the discovery of novel anti-cancer combinations an additional year to May 2012. The original deal signed in May 2009, which included an upfront payment of $4 million plus $3 million per year in research support funding, was for two years and set to expire in May 2011. We are pleased to see Novartis continue to push forward in this discovery program with Zalicus. Zalicus is eligible to receive up to $58 million in clinical, regulatory and commercial milestones for each combination that is commercialized under the collaboration.

Amgen

Zalicus continues to leverage the power of its proprietary cHTS combination drug discovery platform by entering into pilot discovery research collaboration with Amgen in December 2009. Amgen licensed non-exclusive access to the cHTS drug discovery platform focused on identifying synergistic combinations for two oncology targets, for a limited period of nine months (September 2010), with the option of extending the term and scope of the collaboration. Zalicus has received a $750k license fee for this trial period. In September 2010, Amgen agreed to extend the collaboration for an additional year. This should allow Zalicus to earn additional revenues from milestones and reimbursement in 2011. Management's goal is to sign a loner-term agreement with Amgen by the end of the year in a similar size and scope to the Novartis deal discussed above.

PIPELINE



VALUATION

Zalicus is in an enviable position within the biotechnology industry. The company has an approved product on the market in Exalgo, and is collecting royalties from a strong partner in Covidien. The company's pipeline contains Synavive, a mid-stage candidate with proof-of-concept data in a significant market opportunity with rheumatoid arthritis (RA) and osteoarthritis (OA). Zalicus also possess one of the market's leading research and discovery programs in calcium channel programs. Management is focusing the company's early-stage discovery efforts into the development of a new class of analgesics for the treatment of both acute and chronic pain. Finally, the cash position is strong, with $46.5 million on hand at the end of 2010, with the potential to raise additional funds in 2011 through the sale or out-license of non-core candidates for psoriasis (CRx-191) and diabetes (CRx-401), or exercising Term-B or Term-C on its loan with Oxford. Accordingly, we believe the best valuation methodology for Zalicus is a sum-of-parts analysis that takes into account the strong cash flows from Exalgo and the upside in future development from Synavive, the ion channel programs, and potential out-licensing opportunities.

Our sum of parts / NPV analysis for Zalicus yields a total firm value of roughly $260 million, or $3 per share. At the current value of only $185 million we believe the company is under-valued. A detailed analysis of our sum of parts valuation can be found in our initiation report from September 2010, and our follow-up reports published in November 2010 and January 2011. We see upside beyond the $3 level based on positive news from Sanofi on prednisporin, or partnering of the early-stage ion channel program. We rate the shares 'Outperform'.

PROJECTED INCOME STATEMENT

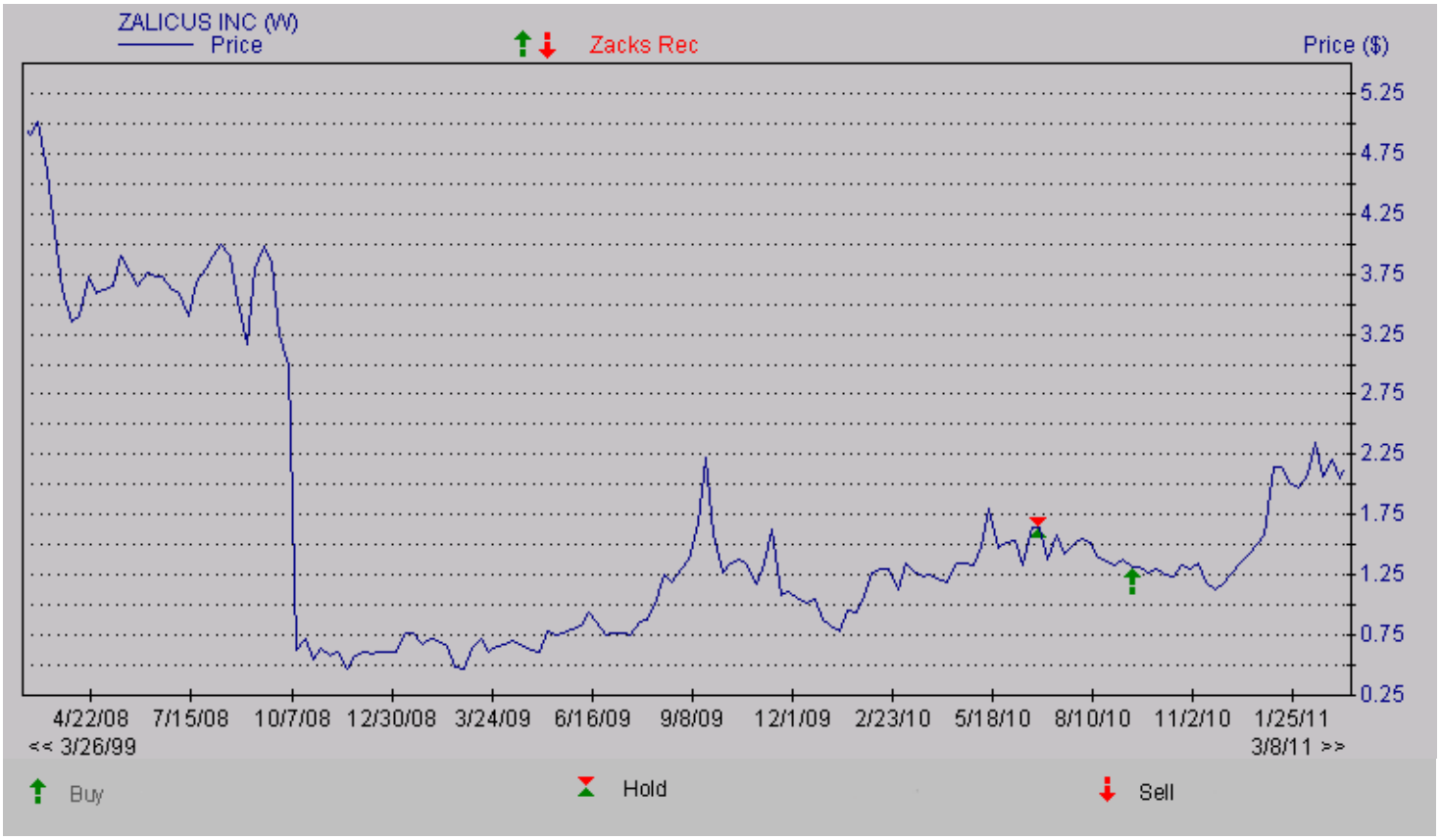
Zalicus, Inc.
Income Statement

	2009 A	2010 A	Q1 E	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E
Collaborations & Grants	**$17.3**	**$45.2**	**$0.8**	**$3.6**	**$0.7**	**$1.5**	**$6.6**	**$10.0**	**$15.0**
YOY Growth	*22.3%*	*161.4%*	*-98.1%*	*95.8%*	*-34.3%*	*63.6%*	*-85.4%*	*51.5%*	*50.0%*
Exalgo Royalty	**$0**	**$1.6**	**$0.7**	**$1.0**	**$1.3**	**$1.8**	**$4.8**	**$10.5**	**$18.8**
YOY Growth	-	-	-	-	-	-	-	-	-
Synavive (CRx-102)	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Total Revenues	**$17.3**	**$46.7**	**$1.5**	**$4.6**	**$2.0**	**$3.3**	**$11.4**	**$20.5**	**$33.8**
YOY Growth	*22.3%*	*170.6%*	*-96.5%*	*58.5%*	*71.5%*	*152.1%*	*-75.6%*	*79.7%*	*64.6%*
General & Administrative	$17.1	$12.1	$2.8	$2.8	$2.9	$3.0	$11.5	$12.0	$12.5
% SG&A	*98.9%*	*25.9%*	*193.1%*	*60.3%*	*145.0%*	*90.4%*	*100.8%*	*58.5%*	*37.0%*
Research & Development	$21.2	$23.0	$5.6	$6.0	$6.8	$7.5	$25.9	$30.0	$30.0
% R&D	*123.0%*	*49.2%*	*386.2%*	*129.3%*	*340.0%*	*225.9%*	*227.0%*	*146.3%*	*88.9%*
Amort & Restruct	($0.4)	$18.7	$4.7	$4.7	$4.7	$4.7	$18.8	$15.0	$12.5
% Other	*-2.6%*	*40.1%*	*324.1%*	*101.3%*	*235.0%*	*141.6%*	*164.8%*	*73.2%*	*37.0%*
Operating Income	($20.6)	($7.1)	($11.7)	($8.9)	($12.4)	($11.9)	($44.8)	($36.5)	($21.3)
Operating Margin	-	-	*-803.4%*	-	-	-	-	-	-
Interest & Other Net	$21.8	($29.2)	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Pre-Tax Income	$1.2	($36.3)	($11.6)	($8.8)	($12.4)	($11.8)	($44.7)	($36.4)	($21.2)
Taxes	($0.1)	(1.2)	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Tax Rate	*-6%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Discontinued Operations	$14.1	$0	$0	$0	$0	$0	$0	$0	$0
Net Income	$15.4	($35.0)	($11.6)	($8.8)	($12.4)	($11.8)	($44.7)	($36.4)	($21.2)
YOY Growth	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-
Reported EPS	**$0.41**	**($0.42)**	**($0.13)**	**($0.10)**	**($0.14)**	**($0.13)**	**($0.50)**	**($0.39)**	**($0.22)**
YOY Growth	-	-	-	-	-	-	-	-	-
Weighted Ave. Shares	37.3	82.6	89.3	89.5	89.7	90.0	89.6	93.0	95.0

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

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