Zacks Small-Cap Research

May 12, 2014
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

scr.zacks.com
10 S. Riverside Plaza, Chicago, IL 60606

InVivo Therapeutics (NVIV-OTCQB)

NVIV: Cash Secured, Human Trial Seeks First Patient…

Current Recommendation	**Neutral**
Prior Recommendation	Buy
Date of Last Change	07/23/2013
Current Price (05/12/14)	$1.17
Target Price	**$2.00**

UPDATE

On May 12, 2014, InVivo Therapeutics reported financial results for the first quarter ended March 31, 2014. The company did not report revenues during the quarter. This was in-line with expectations. Net loss in the quarter totaled $5.1 million, driven by $3.2 million in R&D and $1.8 million in SG&A expense. These were both slightly lighter than our expectations.

On April 28, 2014, InVivo Therapeutics announced something that investors have been waiting on for a very long time – the biocompatible polymer scaffolding has finally entered human clinical trials for the treatment of acute spinal cord injury.

SUMMARY DATA

52-Week High	**$5.67**
52-Week Low	**$1.10**
One-Year Return (%)	**-57.93**
Beta	**1.27**
Average Daily Volume (sh)	**502,427**
Shares Outstanding (mil)	**79**
Market Capitalization ($mil)	**$96**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**28**
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 2014 Estimate	**N/A**
P/E using 2015 Estimate	**N/A**

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

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	0 A	0 A	0 A	0 A	0 A
2014	0 A	0 E	0 E	0 E	0 E
2015					0 E
2016					0 E

Earnings per Share
(EPS is operating earnings)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.20 A	-$0.20 A	-$0.07 A	-$0.07 A	-$0.52 A
2014	-$0.07 A	-$0.06 E	-$0.06 E	-$0.07 E	-$0.24 E
2015					-$0.26 E
2016					-$0.26 E

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Results

On May 12, 2014, InVivo Therapeutics (NVIV) reported financial results for the first quarter ended March 31, 2014. The company did not report revenues during the quarter. This was in-line with expectations. Net loss in the quarter totaled $5.1 million, driven by $3.2 million in R&D and $1.8 million in SG&A expense. These were both slightly lighter than our expectations.

From a cash burn standpoint, InVivo used $4.1 million in cash from operating and investing activities during the first quarter 2014. Operating burn for the previous four quarters came in at $4.3, $4.2, $4.1, and $4.3 million, so operations have been extremely consistent over the past 15 months while the company prepared to initiate its first human clinical trial with the neuro-spinal scaffolding. Cash as of March 31, 2014 totaled $9.8 million.

On May 9, 2014, InVivo completed an underwritten public offering whereby the company sold 14.0 million shares of common stock at $1.15 per share to raise gross proceeds of $16.1 million. Also included in the transaction was 7.0 million warrants exercisable for five years at $1.44 per share. Aegis Capital Corp. acted as sole book-running manager for the offering. As a result, we project cash at June 30, 2014 will be approximately $20.2 million, which we believe is enough to fund operations into late 2015.

IDE Trial Finally Starts

On April 28, 2014, InVivo Therapeutics announced something that investors have been waiting on for a very long time – the biocompatible polymer scaffolding has finally entered human clinical trials for the treatment of acute spinal cord injury. We remind investors that implantation of the Neuro-Spinal Scaffold ("NSS") device in preclinical rodent and primate studies resulted in functional recovery for previously paralyzed animals. Recall some of the impressive videos the company made available in 2011 and 2012 from these studies. The company is hoping these results transition over to humans with the start of this potential revolutionary trial.

InVivo's NSS is made of a porous bioresorbable polymer scaffold comprised of poly ((lactic-co-glycolic acid)-co-poly-(L-lysine)), or PLGA-PLL. The device provides structural support to injured spinal tissue, as well as a supportive matrix for allowing the endogenous healing/repair processes to proceed without risk of bleeding and inflammation creating scar tissue around the injury that might inhibit spinal transmission along the cord. InVivo management believes its device preserves healthy spinal tissue, increasing the chance for functional recovery.

The NSS is designed for use in the most common spinal cord injury – a contusion injury. The NSS is trimmed to fit the contusion and placed into the epicenter of the contusion. After implantation, the scaffold degrades inside the body over a time-course that is intended to favor functional recovery. In preclinical studies, the NSS promoted cell adhesion, neurite sprouting, the growth of remodeled spinal cord tissue containing myelinated axons, and improved motor function in rodent and primate models.

The pilot study is designed to evaluate whether the NSS is safe and feasible for the treatment of complete functional spinal cord injury. This will be determined by no degradation in paralysis level or sensory motor neurological function beyond that typically seen in the ASIA-A subject. We believe this is "low-hanging fruit" in terms of the primary outcome. However, the study will also gather preliminary evidence of clinical effectiveness, to be determined by improvement of ASIA Impairment Scale, sensory scores, motor scores, bladder and bowel function, neurological tests, and The Spinal Cord Independence Measure III.

A total of five patients will be enrolled in this initial pilot study. Patients must be between 18 and 55 year old, and have traumatic spinal cord injury along the thoracic region on the spine (T3-T11) with ASIA-A complete impairment confirmed by neurosurgeon, occurring within past 10 days. The injury must be a non-penetrating contusion injury no less than 4 mm diameter and limited to 2 contiguous vertebral levels.

…Enrolling The Right Patients…

According to 2013 data from the National Spinal Cord Injury Statistical Center, there are an estimated 12,000 acute spinal cord injuries in the U.S. each year. Data from a 2011 annual statistical report created for the Spinal Cord Injury Model Systems shows that 46% of these individuals will be classified as ASIA-A upon admittance to the hospital. Roughly 90% survive one-week post injury. Approximately 35% of all spinal cord injuries are in the thoracic region on the spin (32% between T3-T12). Approximately 70% of these injuries are non-penetrating. Approximately 60% of the patients are between the ages of 18 and 55. This population, approximately 1,600 individuals, is the target market for InVivo's pilot study.

The pilot study is cleared to take place at three sites around the U.S. The initial clinical site will be at The University of Arizona Medical Center in Tucson, AZ under the direction of principal investigator, Ali A. Baaj, MD, Assistant Professor of Surgery and Director of the Spinal Neurosurgery Program at The University of Arizona Medical Center. Additional sites will be announced shortly. We believe opening up additional clinical sites, especially one on the east coast, is extremely important for timely patient recruitment.

After the first patient has been enrolled, InVivo will record the safety and efficacy data noted above at 24 hours, 48 hours, one week, time of hospital discharge, one month, three months, six months, and twelve months. InVivo will be working closely with the FDA on data analysis, and if the safety looks good at three months, then the trial will be cleared to allow enrollment of the second patient. After the second patient clears the three month safety assessment, the trial will be allowed to enroll the third patient, and so on and so forth until five patients are enrolled. As of now, we are not expecting the FDA to allow accelerated enrollment of patients 3-5 based on the safety and efficacy data from the first two patients, but that is certainly a possibility and something the company will aggressively pursue if the data looks good. This is something we spoke with CEO Mark Perrin about on April 28th.

However, assuming no accelerated enrollment, the pilot study will take 18 months to complete, with full twelve-month patient data on all five patients coming in roughly 28 to 30 months. Following successful completion of the pilot study, InVivo expects to conduct a pivotal study to obtain FDA approval to commence commercialization under a Humanitarian Device Exemption (HDE). We remind investors that InVivo received a Humanitarian Use Device (HUD) designation for the NSS in April 2013.

…Reasons To Be Bullish…

Management believes the NSS is a potential $500 million product in acute spinal cord injury. We concur. Although the initial inclusion criteria for the pilot study are strict, we believe if the NSS works, neurosurgeons will use the device in almost all non-penetrating spinal cord injuries, regardless of thing like ASIA impairment level and injury location. This brings the market up from roughly 1,600 patients per year to more like 6-8,000 patients per year. Of course, as of now we are excluding the nearly 300,000 American's with injuries greater than 10 days old. In time, InVivo may expand the use of the NSS to these "chronic" patients, perhaps in combination with neural/spinal cord stem cells.

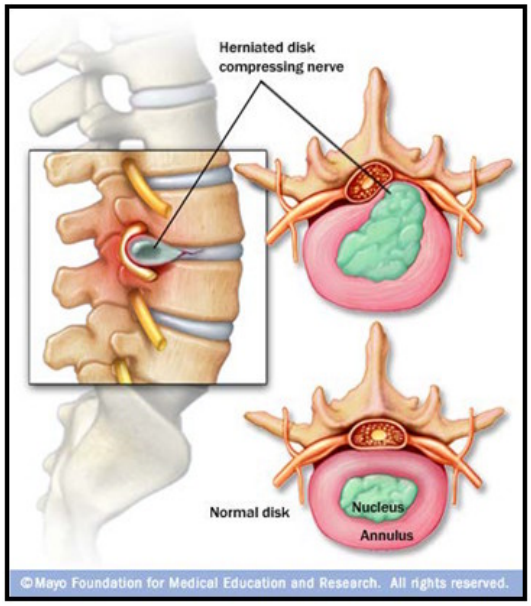
According to the NSCISC's February 2013 report "Spinal Cord Injury Facts and Figures at a Glance," (i) during the first year, average "cost of care" ranges from $340,787 to $1,044,197, depending on the severity of the injury, (ii) the net present value to maintain a quadriplegic injured at age 25 for life is $4,633,137, and (iii) the NPV to maintain a paraplegic injured at age 25 for life is $2,265,584. Because these costs place a tremendous financial burden on families, insurance providers, and government agencies, and because of the HUD designation, we believe a cost of $100,000 is fair (and actually quite conservative).

As for commercialization, according to industry statistics, nearly 80% of all spinal cord injuries are treated at 75 Level 1 trauma centers around the U.S. We believe the company can effectively target these 75 centers with 10 to 20 direct representatives. InVivo's scaffolding is designed to complement the current standard of care for an acute spinal cord injury, not replace it. The sales forced, armed with pivotal human efficacy data and promoting the product under that type of marketing message, should have enormous success.

We are being aggressive here because the scaffolding is design to be complementary to standard-of-care or new treatment options that might incorporate the use of neural stem cells. We expect next-generations variations of the scaffolding will be designed to specifically incorporate advancing regenerative medicine technologies. As such, $500 million seems easily doable – assuming the NSS works.

Waiting For An Update On The Hydrogel

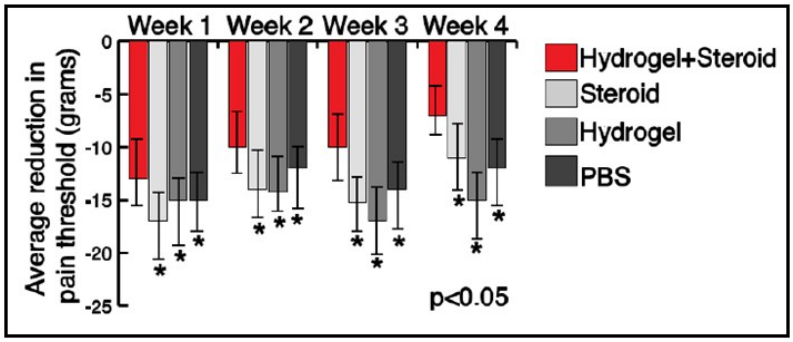
With respect to the hydrogel, the company is current looking for development partners and non-dilutive capital to push forward. According to the company's SEC filings, InVivo is looking at potential acquisitions that will maximize the value of this technology in combination with approved and developmental therapeutics. The hydrogel platform encompasses a broad design space with highly tunable chemical and physical properties that allow for precise control of gel formation/degradation and drug release rates. Management is exploring the use of this platform in several clinical indications including neurotrauma, postoperative pain, radicular pain, and oncology. Furthermore, there are several opportunities being explored in the neurotrauma space for which the hydrogel technology could be developed as a device only (e.g. dural sealants, dural grafts, adhesion barriers). For example, the primary application for the hydrogel in neurotrauma might be in treating peripheral nerve pain and in acting as a dural sealant following spinal and cranial surgery requiring the opening of the dura mater.



Disk herniation and radiculopathy are two major causes of peripheral nerve pain. In lumbar radiculopathy, pain or numbness of the buttock and leg is typically caused by compression of the lumbar spinal nerve root (sciatica). Disc herniation, stenosis, osteophyte formation, spondylolithesis, and other degenerative disorders all lead to this type of pain. Existing treatment options include NSAIDs and epidural steroid injections. However, these injections are short-lived and carry risk of side effects. The hydrogel is designed to function as a therapeutic drug delivery depot that provides sustained local release of drugs that provide pain relief, such as glucocorticoid or corticosteroids, for weeks beyond existing depot formulations.

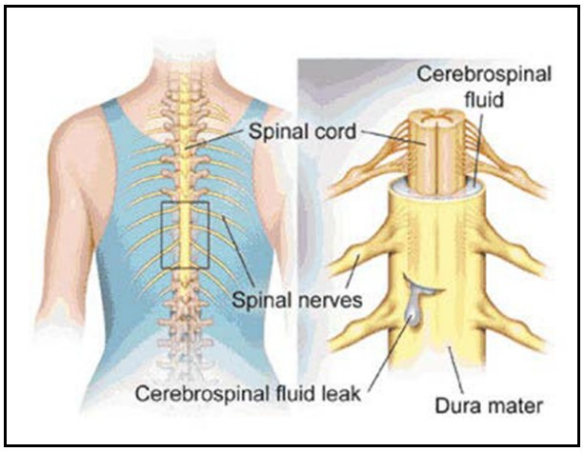
Lots of companies have injectable sustained release pain medications. This is not a revolutionary approach. However, InVivo believes its proprietary poly-ethylene glycol (PEG) formulation Hydrogel has a number of unique advantages over conventional sustained-release depot formulations based on control and residence time, pharmacokinetics and pharmacodynamic properties, and, most importantly, a lack of swelling post injection (more on that below). Treatment for peripheral nerve pain is a pretty sizable market opportunity in the U.S., as 3-4% of the population suffers from chronic lower back pain. InVivo estimates there were nearly 9 million epidural steroid injections in the U.S. in 2010. It's a $300 billion dollar market! Conventional injections last four to six weeks, at best. InVivo's could last 3 months.

The data here looks very good. InVivo has presented preclinical data conducted by Geisinger in rodent sciatic nerve ligation model. The four week study compared InVivo's hydrogel plus methylprednisolone to the hydrogel alone, methylprednisolone alone, and a control (phosphate buffered saline). Results can be seen in the figure below comparing four groups to baseline "pre-ligation". Results show a clear and statistically significant move back to baseline "no pain" for the combination hydrogel + MPSS product vs. all other components. What's very interesting is that MPSS, the current standard of care, really offers no statistically significant difference from the PBS control. Thus investors can get a sense of the opportunity here for InVivo – the standard of care is pretty terrible but still generates billions in sales. With a clearly superior alternative, InVivo's combination hydrogel + MPSS product could become the new standard of care and generate pretty significant sales.



In use of the Hydrogel as a dural sealant, InVivo would be going squarely up against existing dural sealant products, for example Covidien's DuraSeal. During neurosurgical procedures, preventing the leakage of cerebrospinal fluid (CSF) is essential to reduce potential adverse events such as infection and to ensure positive patient outcomes. To achieve a watertight closure, surgeons can use a product like DuraSeal. The product is approved as an adjunct to suturing – and it's approved as a medical device (not a therapeutic). Covidien describe the product as an innovative synthetic (PEG) absorbable hydrogel sealant that lasts 4 to 8 weeks. CSF leak is a major complication following spinal or cranial surgeries. According to Covidien, there are 1.5 million spinal surgeries performed in the U.S. each year, about 10% of which require a dural sealant. This complicating alone can add $15,000 in additional costs to the healthcare system.

An issue with DuraSeal is potential swelling of the gel post-injection. This is a very tricky situation given the tight location of the spinal cord and potential neurological or physical impact that swelling or added pressure could have on the patient. InVivo believes their proprietary formulation of PEG could offer similar efficacy to DuraSeal but with less risk of complications resulting from swelling. We were unable to peg an exact sales number for DuraSeal at Covidien, but with an estimated 150,000 spinal surgeries with CSF leak per year, we see a pretty meaningful opportunity here.



Unfortunately, the current management thinks that a third party holds intellectual property, including patent rights that may be important or necessary to the development and commercialization of certain hydrogel products. Accordingly, it may be necessary for InVivo to use the patented or proprietary technology of third parties to commercialize its hydrogel products, in which case management would be required to obtain a license from such third parties or acquire such intellectual property rights. Frank never mentioned this in our conversations.

Investors have often asked why we do not model sales of the hydrogel product similarly to how we have mapped out sales of the scaffolding above. There are three reasons: Firstly, we have yet to see any regulatory applications in the U.S. from the company seeking approval to begin clinical studies with the hydrogel. Secondly, the company must secure intellectual property around the hydrogel. Until we see IP secured and applications filed, we believe it is safe to assume the hydrogel remains squarely on the back-burner for InVivo. Lastly, even if the company secures the necessary IP and files an IDE to begin human studies with the hydrogel, with cash to October 2014, InVivo simply does not have the financial capability to push the hydrogel forward without a development partner.

Conclusion

Announcing the start of the pilot study is clearly a positive event for InVivo. It has been nearly three years since the filing of the first IDE application. The next step for the company is to find and enroll the first patient. This will be an open-label design, so we expect that the company will keep investors in the loop as the three, six, and twelve-month data becomes available from this first patient.

The Neuro-Spinal Scaffold in the HUD population easily looks like a $500 million drug. If that's the case, InVivo's stock is certainly very attractive at a market capitalization of only $110 million today ($125 million fully-diluted). We think a valuation inflection may come upon the public release of the three-month safety and initial efficacy data from this pilot study. That could be in the beginning of August 2014.

We are warming to the InVivo story. As noted above, initiation of the pilot study is clearly a positive event. We believe there are a number of upcoming events over the next six to nine months that will help define InVivo's future. We encourage investors to stay tuned for the next update.

PROJECTED FINANCIALS

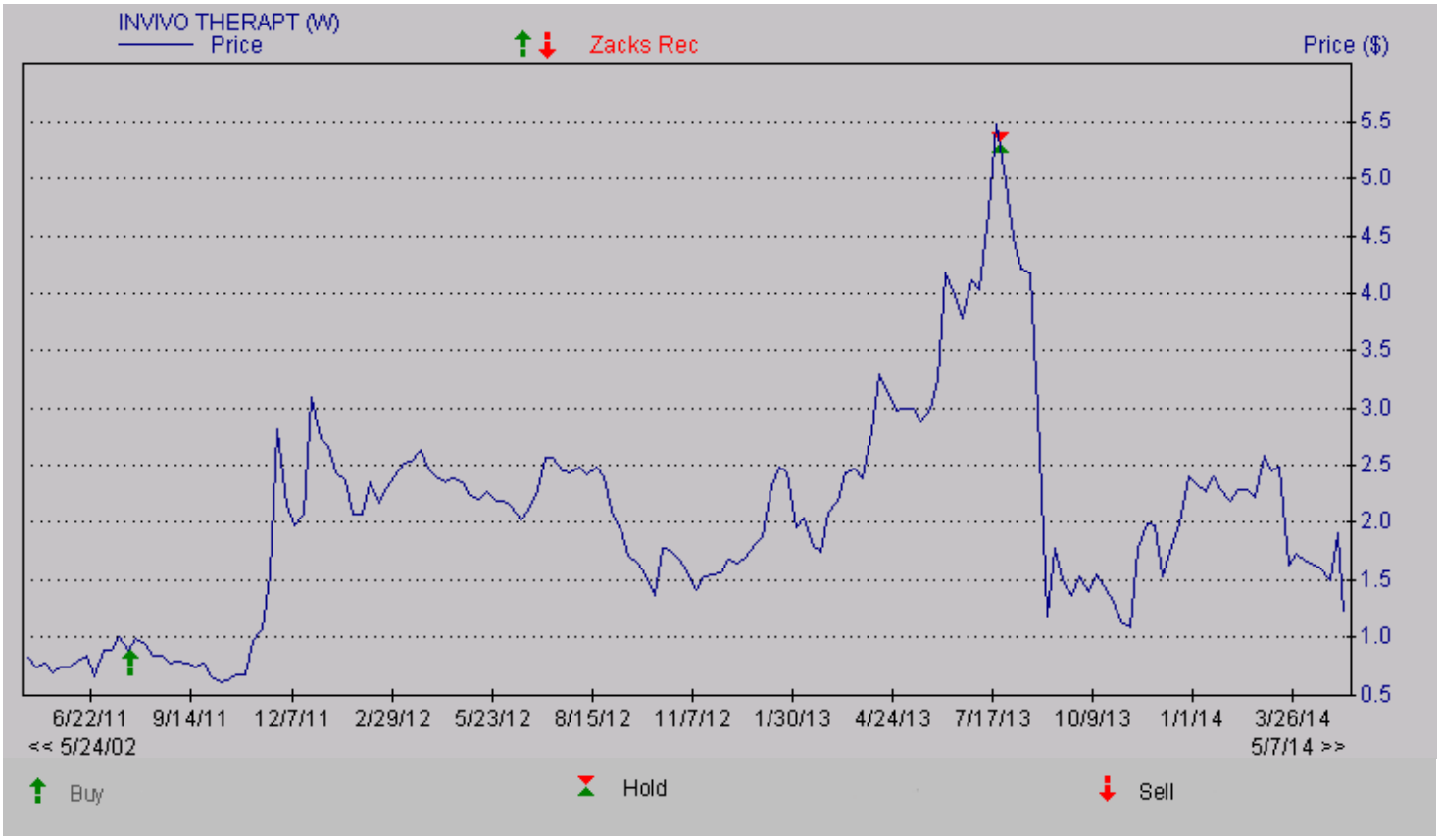
InVivo Therapeutics Holdings Corp.
Income Statement

InVivo Therapeutics	2013 A	Q1 A	Q2 E	Q3 E	Q4 E	2014 E	2015 E	2016 E
Product Sales	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-
Collaborative & Licensing	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
Total Revenues	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-					-	-	-
Cost of Goods / Services	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-					-	-	-
R&D	$10.5	$3.2	$3.5	$3.8	$4.2	$14.7	$17.5	$20.0
SG&A	$8.5	$1.8	$2.0	$2.0	$2.1	$7.9	$8.5	$9.0
Operating Income	($19.0)	($5.1)	($5.5)	($5.8)	($6.3)	($22.7)	($26.0)	($29.0)
Operating Margin	-					-	-	-
Net Other Income	($19.8)	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	($0.1)	($0.1)
Pre-Tax Income	($38.8)	($5.1)	($5.5)	($5.8)	($6.3)	($22.8)	($26.1)	($29.1)
Taxes	$0	$0	$0	$0	$0	$0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0.0%*	*0.0%*
Net Income	($38.8)	($5.1)	($5.5)	($5.8)	($6.3)	($22.8)	($26.1)	($29.1)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($0.52)**	**($0.07)**	**($0.06)**	**($0.06)**	**($0.07)**	**($0.24)**	**($0.26)**	**($0.26)**
YOY Growth	-					-	-	-
Wt. Ave Shares Outstanding	74.0	74.2	90.0	94.0	95.0	96.0	100.0	110.0

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

© Copyright 2014, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



© Copyright 2014, Zacks Investment Research. All Rights Reserved.

DISCLOSURES

The following disclosures relate to relationships between Zacks Small-Cap Research ("Zacks SCR"), a division of Zacks Investment Research ("ZIR"), and the issuers covered by the Zacks SCR Analysts in the Small-Cap Universe.

ANALYST DISCLOSURES

I, Jason Napodano, CFA, CFA, hereby certify that the view expressed in this research report accurately reflect my personal views about the subject securities and issuers. I also certify that no part of my compensation was, is, or will be, directly or indirectly, related to the recommendations or views expressed in this research report. I believe the information used for the creation of this report has been obtained from sources I considered to be reliable, but I can neither guarantee nor represent the completeness or accuracy of the information herewith. Such information and the opinions expressed are subject to change without notice.

INVESMENT BANKING, REFERRALS, AND FEES FOR SERVICE

Zacks SCR does not provide nor has received compensation for investment banking services on the securities covered in this report. Zacks SCR does not expect to receive compensation for investment banking services on the Small-Cap Universe. Zacks SCR may seek to provide referrals for a fee to investment banks. Zacks & Co., a separate legal entity from ZIR, is, among others, one of these investment banks. Referrals may include securities and issuers noted in this report. Zacks & Co. may have paid referral fees to Zacks SCR related to some of the securities and issuers noted in this report. From time to time, Zacks SCR pays investment banks, including Zacks & Co., a referral fee for research coverage.

Zacks SCR has received compensation for non-investment banking services on the Small-Cap Universe, and expects to receive additional compensation for non-investment banking services on the Small-Cap Universe, paid by issuers of securities covered by Zacks SCR Analysts. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, equity research, investment management, non-deal road shows, and attendance fees for conferences sponsored or co-sponsored by Zacks SCR. The fees for these services vary on a per client basis and are subject to the number of services contracted. Fees typically range between ten thousand and fifty thousand USD per annum.

POLICY DISCLOSURES

Zacks SCR Analysts are restricted from holding or trading securities placed on the ZIR, SCR, or Zacks & Co. restricted list, which may include issuers in the Small-Cap Universe. ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Each Zacks SCR Analyst has full discretion on the rating and price target based on his or her own due diligence. Analysts are paid in part based on the overall profitability of Zacks SCR. Such profitability is derived from a variety of sources and includes payments received from issuers of securities covered by Zacks SCR for services described above. No part of analyst compensation was, is or will be, directly or indirectly, related to the specific recommendations or views expressed in any report or article.

ADDITIONAL INFORMATION

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but are not guaranteed as to be accurate nor do we purport to be complete. Because of individual objectives, this report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed by Zacks SCR Analysts are subject to change without notice. Reports are not to be construed as an offer or solicitation of an offer to buy or sell the securities herein mentioned.

ZACKS RATING & RECOMMENDATION

ZIR uses the following rating system for the 1093 companies whose securities it covers, including securities covered by Zacks SCR:
Buy/Outperform: The analyst expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters.
Hold/Neutral: The analyst expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters.
Sell/Underperform: The analyst expects the company will underperform the broader U.S. Equity market over the next one to two quarters.

The current distribution is as follows: Buy/Outperform- 16.8%, Hold/Neutral- 75.7%, Sell/Underperform – 6.7%. Data is as of midnight on the business day immediately prior to this publication.