Zacks Small-Cap Research

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Nuvo Research, Inc. (T.NRI - TSX)

T.NRI: Victory Against Mallinckrodt, WF10 Trial Now Fully Enrolled…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	05/05/2014
Current Price (09/16/14)	$3.28
Target Price	**$7.50**

UPDATE

Nuvo Research has reached a full settlement with Mallinckrodt Inc. relating to Nuvo's license to Mallinckrodt on the right to market and sell Pennsaid and Pennsaid 2% in the U.S. The settlement calls for all U.S. rights to Pennsaid and Pennsaid 2% to be returned to Nuvo along with a payment of $10 million. The company is now free to renegotiate a licensing deal with a new company that should bring in even more non-dilutive capital in the form of an upfront payment.

Other recent important news includes the completion of enrollment in the Phase 2 trial of WF10 for the treatment of allergic rhinitis. We believe that at the current stock price the market does not fully appreciate the potential of Pennsaid 2% or WF10, thus Nuvo remains a top pick in the small cap specialty pharmaceutical space.

SUMMARY DATA

52-Week High	**5.73**
52-Week Low	**1.58**
One-Year Return (%)	**97.2**
Beta	**N/A**
Average Daily Volume (sh)	**19,658**
Shares Outstanding (mil)	**10.2**
Market Capitalization ($mil)	**33.5**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**N/A**
Insider Ownership (%)	**N/A**
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	$2.3 A	$3.3 A	$9.1 A	$3.7 A	$18.4 A
2014	$2.8 A	$3.9 A	$3.4 E	$3.4 E	$13.4 E
2015					$14.0 E
2016					$18.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2013	-$0.39 A	-$0.25 A	-$0.34 A	-$0.22 A	-$1.18 A
2014	-$0.31 A	-$0.23 A	-$0.28 E	-$0.31 E	-$1.13 E
2015					-$1.01 E
2016					-$0.69 E

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WHAT'S NEW

On September 8, 2014, Nuvo Research (NRIFF) announced they had reached a settlement in its litigation with Mallinckrodt, Inc. (MNK) that results in Nuvo retaining all U.S. rights to Pennsaid® and Pennsaid® 2% along with a cash payment of $10 million. This followed the announcement earlier in the month that the company has completed enrollment in the Phase 2 clinical trial to investigate the safety and efficacy of WF10 for the treatment of refractory allergic rhinitis. Below, we will extrapolate on our bullish thesis in regards to Nuvo as it pertains to the recently announced news. We believe that the market is greatly underestimating the potential for both Pennsaid® 2% and WF10, and at the current price Nuvo remains a top pick in the small cap specialty pharmaceutical sector.

Victory for Nuvo in the Mallinckrodt litigation

News that Nuvo had reached a settlement with Mallinckrodt was not entirely unexpected, as the case was never likely to go to trial. We believe that Nuvo ended up with exactly what it wanted with the settlement, which calls for all U.S. rights to Pennsaid® and Pennsaid® 2% reverting to Nuvo along with a handsome $10 million payment.

As a reminder, Nuvo originally entered into a partnership with Mallinckrodt in June 2009, at which time the company granted Mallinckrodt exclusive rights to market and sell Pennsaid® in the U.S. Concurrently, the two companies agreed to a development plan for Pennsaid® 2%, with Mallinckrodt assuming full responsibilities for all development activities related to Pennsaid® 2%. A Phase 2 trial examining the effect of Pennsaid® 2% in knee osteoarthritis (OA) concluded in June 2011, with positive results being reported showing Pennsaid® 2% met the primary endpoint of reducing knee OA pain.

The development plan the two companies had signed called for two Phase 3 clinical trials for Pennsaid® 2% to begin no later than February 2011. If the timeline was not met, Nuvo had the right to terminate the licensing agreement and take back U.S. rights to both Pennsaid® and Pennsaid® 2%. Mallinckrodt decided that instead of filing a new drug application (NDA) based on the results of two Phase 3 clinical trials that the development plan had called for, a supplementary new drug application (sNDA) would instead be filed based on the data from the Phase 2 clinical trial. In addition, Mallinckrodt requested that Nuvo alter the development plan agreement to reflect this new strategy, which Nuvo refused to do.

The reason Nuvo did not wish to move forward with an sNDA was two-fold: 1) the Phase 2 clinical trial was not powered as a pivotal trial to support approval, thus the label would most likely not be as broad as the label for the first-generation Pennsaid®, and 2) not having data from pivotal Phase 3 clinical trials would prevent Nuvo from being able to seek regulatory approval for Pennsaid® 2% outside of the U.S.

Mallinckrodt filed the sNDA for Pennsaid® 2% in May 2012, after which the FDA requested they refile it as a full NDA, which the FDA accepted for review in July 2012. Mallinckrodt received a complete response letter (CRL) to the NDA in which the FDA requested the completion of a pharmacokinetic (PK) study comparing Pennsaid® 2% to Pennsaid®, thus further delaying the approval of Pennsaid® 2%. After completing the requisite study, Mallinckrodt submitted the results to the FDA in August 2013, and on January 16, 2014, the FDA approved the sale and marketing of Pennsaid® 2% in the U.S.

However, because Mallinckrodt did not perform the Phase 3 studies, Pennsaid® 2% was approved for the "pain of knee OA", as opposed to the larger and broader indication, "treatment of the signs and symptoms of knee OA", which was the approved indication for Pennsaid®.

Nuvo commenced formal legal proceedings against Mallinckrodt in August 2013 in which the company accused Mallinckrodt of breaching the U.S. licensing agreement, specifically by failing to conduct the Phase 3 clinical trials, negligence in the Phase 2 trial by not performing the proper PK studies, and not putting forth requisite sales efforts for Pennsaid® in the U.S.

The litigation was seeking at least $100 million in damages along with the termination of the U.S. licensing agreement and full rights to Pennsaid® and Pennsaid® 2% reverting to Nuvo. We believed all along that the case would never make it to trial as Nuvo had too strong of a case and we believed that a fair settlement would be for the rights to the Pennsaid® franchise to revert to Nuvo along with damages in the $10 million range. It appears that we were pretty accurate in our forecast.

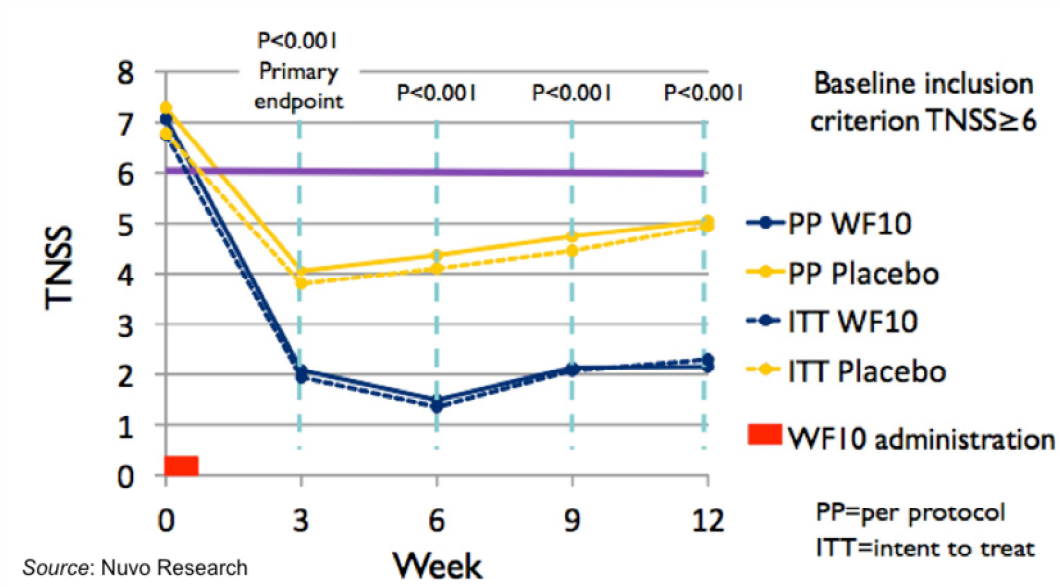
The question now turns to whom Nuvo will partner with for Pennsaid® 2% and what that deal will look like. When surveying the specialty pharmaceutical landscape, it is hard to come up with a better potential partner for Nuvo than Depomed (DEPO), as they recently completed a $345 million convertible note offering, meaning they have significant capital to deploy and they have stated they are interested in using the money for "potential acquisitions and strategic transactions". In addition, Depomed currently markets two diclofenac products: Zipsor®, diclofenac liquid filled capsules for the relief of mild to moderate pain in adults, and Cambia®, diclofenac for the treatment of migraine headaches. Pennsaid® 2%, diclofenac gel for the treatment of knee OA pain, would certainly fit right in with Depomed's portfolio.

Regardless of which company Nuvo ends up partnering with, we believe any deal is likely to bring in approximately $20-30 million upfront with royalties in the high teens to low-twenties (Nuvo was receiving 20% royalties from Mallinckrodt). A deal for Pennsaid® 2% is likely to happen over the very near-term, as Nuvo would like to get the drug back on the market as soon as possible. With the $10 million payment from Mallinckrodt and the potential for an additional $20-30 million from a Pennsaid® 2% licensing deal, along with the $10 million that was reported on the balance sheet at the end of the second quarter, Nuvo could have close to $40 million in cash at the end of 2014. The current market capitalization based on basic share count is a bafflingly low $36 million, and we haven't even discussed Phase 2 asset, WF10.

WF10 Phase 2 trial is fully enrolled

Nuvo recently announced that the Phase 2 trial examining the safety and efficacy of WF10 for the treatment of refractory allergic rhinitis is fully enrolled. As a reminder, this is a 16-week randomized, double blind, placebo controlled study that is examining a regimen of once daily infusions for five consecutive days of either WF10 or its main constituents (sodium chlorite and sodium chlorate) relative to saline control in patients with multiple airborne allergies who suffer from moderate to severe allergic rhinitis. The trial will measure total nasal symptom score (TNSS) and other secondary endpoints. The trial is expected to be completed in the fourth quarter of 2014 with topline results anticipated in the first quarter of 2015.

The results from the 2010 Phase 2 trial of WF10 for the treatment of allergic rhinitis showed that the improvement in TNSS (which is the sum of individual scores assigned by patients for sneezing, rhinorrhea, congestion, and nasal itching) was much greater for WF10 treated patients than for placebo treated patients ($P < 0.001$).



The development plan for WF10 will be based upon the results of the Phase 2 trial. Specifically, by examining both WF10 and its constituents, Nuvo is hoping to gain better insight into the mechanism of action by better understanding the active component of WF10. In addition, the company will need to perform dosing studies to determine the minimum effective dose. For both Phase 2 trials, WF10 was administered as a once daily 90-minute infusion for five consecutive days at a dose of 0.5 mL/kg body weight. Obviously, getting the dose down to the smallest number possible would be optimal as visiting a doctor's office for five consecutive days could be problematic for some patients.

While needing to go to a doctor's office for five consecutive days may not be ideal, a look at a few case reports offers tantalizing possibilities for WF10. In the patent covering the use of WF10 for treating allergic asthma, allergic rhinitis, and atopic dermatitis (US Patent 8435568) there are four case reports of patients who were treated with WF10 on a compassionate use basis with their results being very encouraging:

- Patient #1: A male patient, currently 51 years of age, had a 25-year history of allergic rhinitis and allergic bronchial asthma. The patient had previously tried antihistamines, histamine h1 antagonists, triamcinolone injections, and inhaled cromolyn sodium. WF10 was administered through 4 daily infusions over a 6-day period, with the patient reporting no measurable effects during the treatment period. Approximately 10 days after the start of the infusions the patient was abruptly free of any symptoms of allergic rhinitis and asthma. This continued for two years after which the therapy was repeated biannually with the same doctor and the results were reproduced each time (this regimen was repeated five times). Blood analysis was conducted on the patient, with a significant reduction seen in the expression of interleukin-8 (IL-8) and MIP-1a after WF10 treatment along with an overall reduction in IL-1, TNF-α, and IP10.

- Patient #2: A female patient, currently 59 years of age, was initially diagnosed with allergic rhinitis and bronchial asthma in 1996. Her otorhinolaryngologist did not recommend allergy shots due to the patient being allergic to so many different allergens. The patient used a number of medications prior to the administration of WF10 that included fexofenadine, natriumcromoglicat, azelastin, and cortison. In June 2006 the patient was administered WF10 as a half dose on day 1, full doses on days 2-4, and another half dose on day 5. The patient reported her condition on a scale from 1-6, with 1 being the best and 6 the worst. On day 7 she reported a score of 3, day 8 a score of 2, day 15- no score but a significant improvement noted, and on day 20 a score of 2. The improvement in the patient's condition continued through the rest of 2006 and 2007 with no additional medications required. Symptoms returned in 2008 and the patient was subsequently treated again with WF10.

- Patient #3: A female patient, currently 59 years of age, presented with allergic rhinitis and allergic bronchial asthma, with an initial diagnosis being made in 1990. The patient had tried several medications previously to control symptoms that included levocetirizin, natriumcromoglicat, and azelastin. WF10 was administered in September 2006 with once daily infusions over five days. By day 19 the patient reported a significant overall improvement in her general condition, with the patient being symptom free for the remainder of 2006. Symptoms returned in 2007 but the patient reported they were milder than before WF10 treatment.

- Patient #4: This patient had experienced annual allergy symptoms for 25 years and had tried eye drops, nasal sprays, antihistamines, and homeopathic and naturopathic treatments with nothing helping other than nasal cortisone spray. The patient received five daily infusions of WF10 in February 2006. At the start of treatment the patient reported no impression of improvement, but as allergy season progressed the patient reported that symptoms were not as pronounced as in previous years. While the symptoms did not disappear entirely, they were considerably less obtrusive.

What these case reports hint at is the possibility of a long-term alleviation of allergy symptoms with only a few days' worth of treatment with WF10. Thus, it could be possible to treat patients with one cycle of WF10 every one to two years to alleviate allergic reactions including rhinitis, conjunctivitis, and asthma. In addition, the only adverse side effects seem to be associated with the infusion and not the drug, with no chronic side effects ever having been observed. So while a trip to the allergist's office for five consecutive days sounds like an impediment to the wide acceptance of the drug, relief of symptoms for one to two years would most likely make it more palatable to most patients.

…WF10 matches up well with other immunotherapies…

WF10 is an immunotherapy in that the current understanding of WF10's mechanism of action is that it is immunomodulatory and may interact with macrophages to rebalance improperly functioning immune systems. Additional types of allergy immunotherapies include allergy shots, sublingual immunotherapy, and an immunotherapy platform being developed by the biopharmaceutical company Circassia.

Allergy shots are a form of immunotherapy that work by exposing the immune system to minute quantities of allergen over an extended period of time to help decrease sensitivity to allergens. The shots typically result in lasting relief even after the treatment has stopped. There are two phases to allergy shots: build-up phase, where a patient receives injections with increasing amounts of allergen one to two times per week for three to six months, and the maintenance phase, where the interval between shots is increased to every two to four weeks. This typically continues for three to five years.

While allergy shots have been shown to be effective in a large number of patients there are drawbacks, which include reactions at the injection site, the need to go to the doctor's office for injections one to two times per week for an extended period of time, and the risk of anaphylactic shock, which is a potentially life threatening reaction that can include swelling in the throat, wheezing, nausea, and dizziness.

In 2014, the FDA approved three sublingual allergy medications (Ragwitek®, Grastek®, and Oralair®) that use the same allergens present in allergy shots but are administered in tablets that dissolve under the tongue. The main advantage of these medications is that, aside from the first administration that must be taken at a doctor's office, they can be taken at home. Another advantage of these products is that shots are not required, thus there is no injection site reaction or issues regarding trypanophobia (fear of needles).

A significant disadvantage to currently available allergy immunotherapies is that the treatments are highly specific. For allergy shots, an allergist must first run a series of tests to determine exactly what the patient is allergic to so that the shots can be tailored specifically for that individual. This increases the cost associated with allergy shots. For the newly approved sublingual medications, each product contains specific allergens such that patients who have allergies to multiple different classes of allergens would need to take multiple products, thus increasing the cost of treatment.

The clinical stage biopharmaceutical company Circassia is developing another type of allergy immunotherapy. The company has developed a series of peptide immune-regulatory epitopes (SPIREs) that work to inhibit the cells involved in triggering an immune response. The lead product, Cat-SPIRE, was developed for the treatment of cat allergies, and is currently in an ongoing Phase 3 clinical trial, with results expected in 2016. Other products under development by Circassia include therapies for dust mite, grass, and ragweed allergies. However, just as with allergy shots and sublingual medications, Circassia's products are highly specific and only treat one type of allergy.

As shown in the following chart, WF10 compares quite favorably with allergy immunotherapies that are currently available as well as those under development.

	Sublingual Immunotherapy	Circassia SPIRE	WF10
Short treatment time frame		✓	✓
Potential for long-term treatment effect	✓	✓	✓
Minimal side effects	✓	✓	✓
Covers a broad range of allergens			✓

***Source:* David Bautz, Zacks Investment Research**

…The market is assigning no value to WF10…

Investors are clearly excited about novel allergy immunotherapies, as shown by Circassia's initial public offering in March 2014 that raised $333 million and the company's current market cap of approximately $550 million. Thus, there is clearly an intense interest in allergy therapeutics that target the underlying cause of the allergic reaction rather than just alleviating symptoms. However, this excitement does not seem to be reflected in Nuvo's current valuation.

Our probability adjusted discounted cash flow model indicates that WF10 is worth approximately $31 million, or $2.50 per share on a fully diluted basis. This is based on the drug costing $1,000 per year, however this may end up being too conservative based on the cost of the new sublingual medications (approximately $250/month). The model also indicates that Pennsaid® 2% is worth approximately $45 million, or $3.75 per share on a fully diluted basis, which is very near the current share price. Thus, even though it is an allergy immunotherapy that targets the underlying cause rather than just masking symptoms, the market is assigning no value to WF10, as Nuvo's fully diluted market cap currently stands at approximately $45 million.

Given the above, it is difficult to understand the exorbitant difference in valuation between Circassia and Nuvo. Granted, Circassia is further along in development than Nuvo, with the lead compound currently in a pivotal Phase 3 trial. However, it is doubtful this warrants a greater than 10-fold difference in valuation and thus we believe this represents a good buying opportunity for those looking to invest in the allergy immunotherapy market.

Conclusion and Recommendation

We were quite pleased to see that Nuvo has settled the litigation with Mallinckrodt and ended up with a very fair settlement, with the company receiving almost exactly what we predicted back in June. Now that Pennsaid® 2% is back under Nuvo's control, we believe that the company will try to get a deal in place reasonably soon with a company that will be committed to fully marketing the product. In addition, we believe the deal will include having the partnering company perform the Phase 3 trials that Nuvo will need to both expand the Pennsaid® 2% label as well as for obtaining regulatory approval overseas. Pennsaid® 2% had approximately $5.5 million in sales in the second quarter of 2014, and we believe that under the direction of a company that is properly marketing the product it could attain peak sales of at least $40 million per year.

As we've stated previously, we believe that at the current price an investor is getting a company with a solid portfolio of revenue producing products with WF10 for free, as the market has assigned little to no value to WF10. Our current sum of parts valuation for Nuvo gives us a target price of $7.50 per share, and based upon the current stock price we continue to rate the stock a Buy.

PROJECTED FINANCIALS

Nuvo Research, Inc.
Income Statement

Nuvo Research, Inc.	2013 A	Q1 A	Q2 A	Q3 E	Q4 E	2014 E	2015 E	2016 E
Revenue from Product Sales	**$4.4**	**$1.2**	**$2.2**	**$1.5**	**$1.5**	**$6.4**	**$5.0**	**$3.0**
YOY Growth	*-50.4%*	-	-	-	-	*43.5%*	*-21.4%*	*-40.0%*
Royalties	**$6.1**	**$1.4**	**$1.5**	**$1.5**	**$1.5**	**$5.9**	**$7.5**	**$13.0**
YOY Growth	*-26.4%*	-	-	-	-	*-3.7%*	*27.7%*	*73.3%*
Licensing Fees	**$7.6**	**$0.1**	**$0.2**	**$0.3**	**$0.3**	**$0.8**	**$1.0**	**$1.5**
YOY Growth	*4.9%*	-	-	-	-	*-89.0%*	*19.5%*	*50.0%*
Research and Contracts	**$0.3**	**$0.1**	**$0.0**	**$0.1**	**$0.1**	**$0.3**	**$0.5**	**$0.5**
YOY Growth	*52.8%*	-	-	-	-	*27.6%*	*44.1%*	*0.0%*
Total Revenues	**$18.4**	**$2.8**	**$3.9**	**$3.4**	**$3.4**	**$13.4**	**$14.0**	**$18.0**
YOY Growth	*-25.3%*	-	-	-	-	*-27.1%*	*4.3%*	*28.6%*
CoGS	$4.8	$1.2	$1.5	$1.3	$1.5	$5.5	$4.0	$2.0
Gross Income	$13.6	$1.5	$2.4	$2.1	$1.9	$7.9	$10.0	$16.0
Product Gross Margin	*74.1%*	*56.1%*	*61.2%*	*61.8%*	*55.9%*	*59.0%*	*71.4%*	*88.9%*
R&D	$7.0	$1.9	$1.5	$2.0	$2.0	$7.4	$9.0	$11.0
% R&D	*38.2%*	*68.4%*	*38.6%*	*58.8%*	*58.8%*	*55.0%*	*64.3%*	*61.1%*
SG&A	$10.1	$2.4	$2.9	$2.5	$2.6	$10.4	$11.0	$12.0
% SG&A	*55.0%*	*86.1%*	*75.0%*	*73.5%*	*76.5%*	*77.3%*	*78.6%*	*66.7%*
Other expenses	$0.6	$0.0	$0.3	$0.5	$0.5	$1.3	$0.5	$0.5
% Payment	*3.1%*	*0.4%*	*6.6%*	*14.7%*	*14.7%*	*9.4%*	*3.6%*	*2.8%*
Operating Income	($4.1)	($2.7)	($2.3)	($2.9)	($3.2)	($11.1)	($10.5)	($7.5)
Operating Margin	*-22.1%*	*-98.7%*	*-59.0%*	*-85.3%*	*-94.1%*	*-82.7%*	*-75.0%*	*-41.7%*
Total Other Income	($6.2)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Pre-Tax Income	($10.3)	($2.7)	($2.3)	($2.9)	($3.2)	($11.1)	($10.5)	($7.5)
Taxes & Other	$0.1	$0.0	$0.0	$0.0	$0.0	$0.1	$0.1	$0.1
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Divs. Of Preferred	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Net Income	($10.4)	($2.7)	($2.3)	($2.9)	($3.2)	($11.2)	($10.6)	($7.6)
Net Margin	*-56.4%*	*-99.5%*	*-59.7%*	*-86.2%*	*-95.0%*	*-83.5%*	*-75.7%*	*-42.2%*
Gain/Loss on trans. of foreign ops	$0.0	$0.1	($0.1)	$0.1	$0.1	$0.2	$0.2	$0.2
Comprehensive Income	($10.4)	($2.7)	($2.4)	($2.8)	($3.1)	($11.0)	($10.4)	($7.4)
Reported EPS	**($1.18)**	**($0.31)**	**($0.23)**	**($0.28)**	**($0.31)**	**($1.13)**	**($1.01)**	**($0.69)**
YOY Growth	*-23.6%*	-	-	-	-	*-4.2%*	*-10.5%*	*-31.6%*
Shares Outstanding	8.8	8.9	10.2	10.3	10.3	9.9	10.5	11.0

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

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HISTORICAL ZACKS RECOMMENDATIONS



Initiations of Coverage – May 5, 2014 @ $3.26 per share

Chart By: Yahoo!, Inc.

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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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