Zacks Small-Cap Research

July 11, 2011
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

www.zacks.com
111 North Canal Street, Chicago, IL 60606

Titan Pharmaceuticals, Inc. (TTNP-OTC)

TTNP: Titan Hits Home Run With Positive Data From Confirmatory Phase 3 Trial With Probuphine…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (07/11/11)	$1.77
Target Price	**$4.50**

UPDATE

This morning Titan released positive data from its second phase 3 confirmatory trial on Probuphine. The data look like a home run to us, with strong statistical significance vs. placebo and non-inferiority to a blockbuster drug in Suboxone. We highlight the data in our report, as well as update timelines for the planned FDA meeting and NDA filing.

Our valuation incorporates a sum-of-parts (NPV) analysis on the royalties from Fanapt ($1 per share) and the risk-adjusted market potential for Probuphine at this stage in its development ($3.50 per share). We are making an aggressive call to buy Titan now that the key clinical trial hurdle has been cleared. We expect a partnership on Probuphine in the next year, with FDA approval in 2013.

SUMMARY DATA

52-Week High	**$2.16**
52-Week Low	**$0.87**
One-Year Return (%)	**76.00**
Beta	**10.80**
Average Daily Volume (sh)	**330,304**
Shares Outstanding (mil)	**59**
Market Capitalization ($mil)	**$104**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**2**
Insider Ownership (%)	**15**
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-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	2.4 A	1.3 A	3.6 A	2.7 A	10.1 A
2011	0.9 A	1.5 E	1.6 E	1.8 E	5.8 E
2012					27.6 E
2013					45.2 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.01 A	-$0.03 A	-$0.01 A	-$0.05 E	-$0.09 E
2011	-$0.08 A	-$0.06 E	-$0.04 E	-$0.03 E	-$0.21 E
2012					$0.23 E
2013					$0.40 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

© Copyright 2011, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Second Phase 3 On Probuphine – A Home Run

On July 11, 2011, Titan Pharma announced positive results from its phase 3 trial, PRO-806, evaluating Probuphine in treating patients with opioid dependence. PRO-806 was the second, confirmatory, phase 3 program evaluating Probuphine vs. placebo for safety and efficacy. The phase 3 clinical trial was a randomized, placebo and active-controlled, multi-center study conducted at 20 sites in the U.S. that treated 287 patients, aged 18 to 60 years across three dosing arms: Probuphine (114 patients), the approved and widely-used sublingual formulation of buprenorphine, Suboxone, (119 patients) and placebo implants (54 patients). Patients were treated for up to 24 weeks and the Probuphine and placebo dosing arms were double-blinded, while the Suboxone arm was open-label. The trial had two primary analyses:

- Cumulative Distribution Function of the percentages of opioid-negative urines over the 24-week treatment period ➔ Results were statistical significance at p<0.0001 vs. placebo, and were consistent with the previously reported phase 3 data (from PRO-805), an published in JAMA, October 2010.

- Cumulative Distribution Function of the percentages of opioid-negative urines incorporating patient self-reported opioid use over the 24-week treatment period ➔ Results were statistical significance at p<0.0001 vs. placebo.

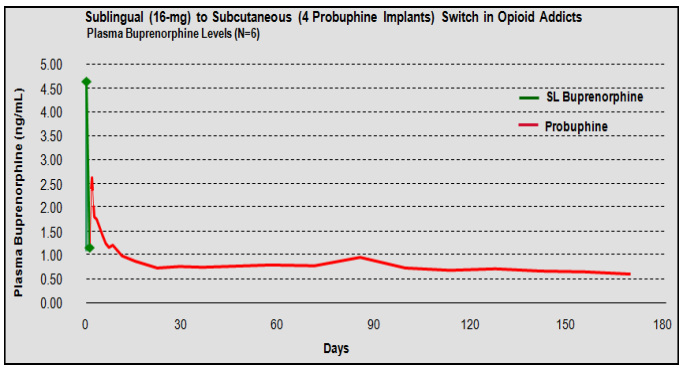
Probuphine also met a key trial secondary objective by demonstrating non-inferiority to Suboxone (12-16 mg) over the 24-week treatment period. We remind investors that Suboxone is used by over 500,000 patients in the U.S. each year, with annualized sales over $1 billion. Worldwide, Suboxone is a $1.2 billion drug.

Pro-806	Probuphine (n=114)	Suboxone (12-16mg) (n=119)	Placebo (n=54)
Negative Urine Samples	31%	33%	?%
Trial Retention	64%	64%	26%

The trial further demonstrated that Probuphine was well tolerated, with an overall safety profile similar to that seen in previous studies. We consider this data to be a "Home Run". Titan now has two positive phase 3 trials, along with open-label follow-up studies, and statistically significant non-inferiority to a blockbuster drug in Suboxone.

Plus, we see several advantages of Probuphine over Suboxone, including:

- ✓ Convenient six month dosing
- ✓ Improved compliance
- ✓ Reduce diversion
- ✓ Constant blood plasma levels
- ✓ No "peaks" and "troughs"
- ✓ Lower total opioid exposure
- ✓ Low withdrawal potential



Titan expects that additional study findings will be reported in the coming weeks followed by a management conference call, as appropriate, and study results will be presented at scientific meetings later this year. Titan plans to request a meeting with the U.S. FDA this fall to review the Probuphine development program and plan for filing a New Drug Application (NDA).

For Additional Information Please See Our Initiation Report Dated June 17, 2011.

VALUATION & RECOMMENDATION

Our Thesis

…Optimistic on Probuphine…

In June 2011, we initiated coverage of Titan Pharmaceuticals with an Outperform rating and $4.50 price target. Our near-term catalyst was the impending release of data from Titan's second, confirmatory, phase 3 trial on Probuphine, dubbed Pro-806. Based on the impressive data from the phase 2 and previous phase 3 study, Pro-805, we suspected the data would be positive.

An important aspect of this second phase 3 trial was the direct comparison of Probuphine with an open-label 12 mg and 16 mg sublingual buprenorphine tablet (Suboxone). Management was attempting to show an overall lower drug exposure and reduced systemic adverse events, improve retention and compliance, and non-inferiority in efficacy and patient satisfaction. Another goal of this trial is to satisfy European regulatory authorities, which often require active comparators prior to approval.

Opioid addiction is a major health and social issue, especially in the U.S. An estimated 7 million people worldwide, nearly 4 million of which are in the U.S., are abusing or addicted to opioids. We note the number of patients in the U.S. receiving methadone treatment in the last several years has remained fairly constant at about 200,000, whereas the number of patients in the U.S. receiving buprenorphine has grown to over 500,000. It is clear the market is shifting from methadone to buprenorphine thanks to its improved characteristics, such as a lower pharmacologic ceiling effect, increased safety margin, and superior therapeutic window of efficacy.

We believe Titan's Probuphine can capture over 20% of the market from the sublingual formulation. We also believe that Titan's commercialization partner can charge a premium price to Suboxone because of the superior characteristics of the drug. This is easily a $500 million opportunity. We also note there is significant upside to this figure if Probuphine is used for the treatment of chronic pain, a multi-billion dollar market in the U.S. We believe that Probuphine could address many of the issues that limit opioid use and encourage opioid abuse today. Buprenorphine is an established and approved analgesic for the treatment of acute and chronic pain. It is approximately 25-50X more potent than morphine, while also having a pharmacologic ceiling effect that provides an increased safety margin.

We see the ideal time to strike a deal for the U.S. and Canadian rights to Probuphine in the fourth quarter 2011. By that time, Titan would have presented top-line data from the Pro-806 program, submitted the full data for publication in a peer-review journal, met with the U.S. FDA for a pre-NDA meeting, and be on track to file the NDA in the first quarter 2012. Our thesis is that partners will want to be involved in the preparation of the application, so a deal will come before the actual filing. At this point it is difficult to say whether Titan will form one global commercialization partner or look to strike regional alliances. Regional deals may make more sense given differences in how opioid addiction is treated in the U.S. vs. the EU, as well as physician comfort with implantable technology like Titan's ProNeura. We believe Titan is looking for a partner with a strong commercial presence in addiction medicine, chronic pain, or specialty CNS disorders.

An upfront payment on Probuphine could bring significant cash to Titan. Management will be looking for upfront cash, along with regulatory and sales-related milestones, and royalties on worldwide sales. Probuphine should be a very profitable drug for Titan's partner. Gross margin should be in the 90%. Roughly 80% of the market can be effectively targeted by a small sales force of only 40-50 representatives. We think management will look for a royalty rate in the twenties, which should allow Titan to become profitable shortly after the Probuphine launch.

…Fanapt Royalties Set To Accelerate…

Besides our bullish stance on Probuphine, we are also starting to see signs that the initial inventory stocking on Fanapt from the first quarter 2010 has been worked through, and we expect that reported sales at Novartis will start to track end user demand by the third quarter 2011. As a reminder, Titan is eligible to receive 8-10% royalty on sales of Fanapt. Novartis paid Vanda Pharmaceuticals $200 million upfront to license the product in October 2009. Vanda is eligible to receive up to an additional $265 million in backend milestones. The hefty deal terms re-enforce our belief that Fanapt is a $250 million product worldwide, and that Titan's royalty will begin to substantially accelerate in the coming quarters as the product takes hold.

Valuation

We see Titan shares as meaningfully under-valued today. We believe that Fanapt alone is worth $1 per share based on the future cash royalty payments. As a reminder, Titan has no ongoing costs associated with these royalties besides the credit facility payment to Deerfield Management, so the net amount is pure cash income to the company. The cash from Fanapt royalties helps management pay for the Probuphine phase 3 program and fund general corporate expenses. We see Fanapt royalties at $4.6 million in 2011, growing to over $16 million per year around the time of the patent expiration in April 2017. The cumulative net present value of these cash flows, assuming a modest 10% discount rate, is $58.9 million. Based on 59.3 million shares outstanding, the Fanapt royalty is worth approximately $1 per share.

Our scenario for Probuphine already includes positive phase 3 data from the Pro-806 trial, along with positive meetings with the FDA later in the year, a new drug application (NDA) in early 2012, and approval in late 2012 with a launch in early 2013. We expect a U.S. deal in the fourth quarter 2011, which should bring upfront cash in the area of $20 to $25 million, a similar approval milestone in late 2013, backend milestone totaling $200 million, and a 20-22% royalty on sales. Under this scenario, we see the net present value (NPV) of Titan's cash from a deal, risk-adjusted backend milestones, and royalties on sales worth $206 million, or $3.50 per share. To account for the risk of this "optimistic" scenario, we are using an aggressive 17.5% discount rate. This is similar to the company's cost of capital based on the March 2011 financing.

Titan exited the second quarter 2011 with an estimated $8 million in cash. We forecast this will be enough to fund operations into the first quarter 2012. Therefore, a deal with upfront cash is important for later this year. If not, Titan may need to raise $10 million or so to keep timelines on track, as well as continue to negotiate with partners from a position of strength. We believe the company only needs an estimated $10 million to make it to cash flow positive operations based on Fanapt and Probuphine royalty payments.

Titan Pharma Sum-Of-Parts Value	
Fanapt Royalties	$59 Million
Probuphine Value	$206 Million
ProNeura Technology	$10 Million
Cash To Breakeven	($10) Million
Total Firm Value	**$265 Million**
Shares Outstanding	59 Million
Price Per Share	**$4.50**

Recent Financing & Cash Position

In March 2011, Titan Pharmaceuticals entered into an agreement with Deerfield Management that provides Titan with $20 million in financing through a five year senior secured credit facility. Interest will accrue on the outstanding balance until maturity at a rate of 8.5% per annum, which is payable on a quarterly basis. The facility is repayable over five years, with 10% of the principal amount due on the first anniversary, 15% on the second anniversary, and 25% of the principal amount on each of the next three anniversaries. Management can elect to pre-pay the outstanding balance at any time at 110% of the remaining principal amount. Deerfield Management has a repayment right at 110% of the principal amount upon a major transaction (which includes but is not limited to the sale of Fanapt or Probuphine). In conjunction with the financing, Titan has agreed to issue six year warrants to purchase 6 million shares of common stock at an exercise price of $1.57 per share. Deerfield Management will also receive 2.5% of the global net sales of Fanapt subject to a repurchase right by Titan.

In April 2011, Titan repaid its current outstanding loan with Oxford Finance Corp totaling roughly $8 million. Management used the proceeds from the Deerfield credit facility to payback Oxford. We estimate the cash balance at the end of the second quarter 2011 will be around $8 million. We project this is enough cash to fund operations into the first quarter 2012. This is right around the time of the NDA filing on Probuphine. We expect Titan to secure a commercialization partnership on Probuphine later in 2011 to generate additional non-dilutive cash.

Upcoming Events

EVENTS TO WATCH	TIMING
Data presentation at NIDA International Forum	**DONE!**
Top-line data from phase 3 (confirmatory) Pro-806 trial	**DONE!**
Additional Data from phase 3 Pro-806 trial	**August 2011**
Meet with U.S. FDA for pre-NDA meeting	**Fall-2011**
Data presentation at International Society of Addiction Medicine	**September 2011**
Data from open-label Pro-811 safety re-treatment study	**Q4-2011**
Data presentation on Pro-806	**Q4-2011**
Sign commercialization partnership on Probuphine	**Q4-2011**
Data presentation at American Academy of Addiction Psychiatry	**December 2011**
File U.S. NDA on Probuphine	**Q1-2012**
U.S. FDA NDA acceptance	**Q2-2012**
U.S. FDA PDUFA on Probuphine	**Q4-2012 / Q1-2013**
Launch Probuphine in the U.S.	**Q1-2013**

Source: Zacks Investment Research, Inc.

PROJECTED FINANCIALS

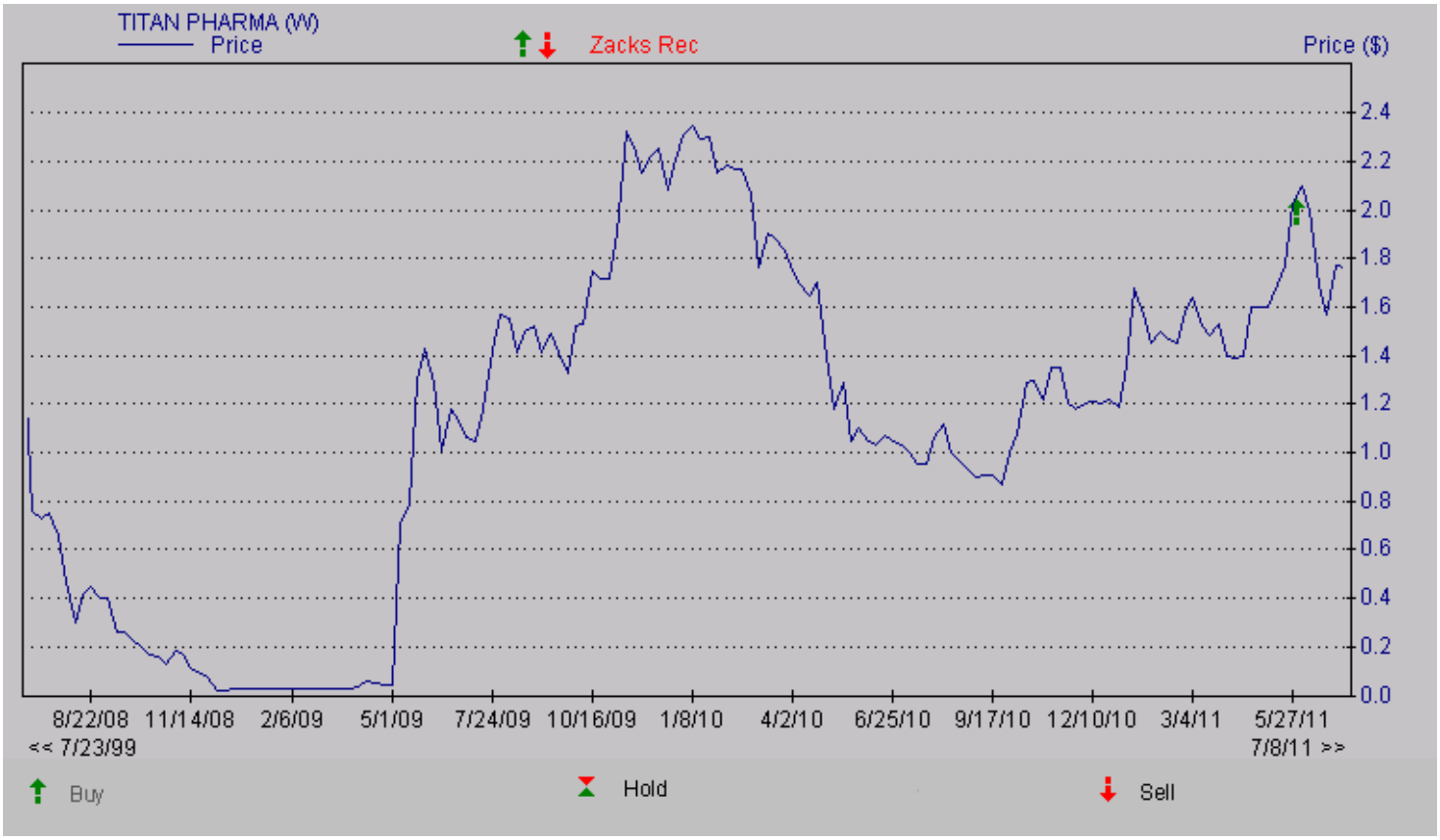
Titan Pharmaceuticals, Inc.
Income Statement

	2009 A	2010 E	Q1 A	Q2 E	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$9.0**	**$18.0**
YOY Growth	-	-	-	-	-	-	-	-	-	*100.0%*
Fanapt Royalty	**$0**	**$2.5**	**$0.7**	**$1.0**	**$1.3**	**$1.6**	**$4.6**	**$7.6**	**$11.2**	**$14.0**
YOY Growth	-	-	*-56.7%*	*1645.5%*	*223.2%*	*292.2%*	*81.4%*	*66.8%*	*47.4%*	*25.0%*
Licensing & Grant Revenue	**$0.1**	**$7.6**	**$0.2**	**$0.5**	**$0.5**	**$0.5**	**$1.7**	**$20.0**	**$25.0**	**$10.0**
Total Revenues	**$0.1**	**$10.1**	**$0.9**	**$1.5**	**$1.8**	**$2.1**	**$6.3**	**$27.6**	**$45.2**	**$42.0**
YOY Growth	-	-	-	-	-	-	*-37.7%*	*338.9%*	*63.8%*	*-7.1%*
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*
R&D	$2.5	$12.9	$3.7	$4.0	$3.0	$2.5	$13.2	$8.0	$10.0	$10.0
% R&D	-	*127.4%*	-	-	-	-	*210.5%*	*29.0%*	*22.1%*	*23.8%*
SG&A	$3.4	$3.3	$0.8	$0.8	$0.9	$0.9	$3.4	$3.6	$4.0	$4.5
% SG&A	-	*32.3%*	-	-	-	-	*54.0%*	*13.0%*	*8.8%*	*10.7%*
Operating Income	($5.8)	($6.0)	($3.6)	($3.3)	($2.1)	($1.3)	($10.3)	$16.0	$31.2	$27.5
Operating Margin	*0%*	*0.0%*	-	-	-	-	*-164.5%*	*58.0%*	*69.0%*	*65.5%*
Total Other Income	($0.1)	($0.8)	($0.9)	($0.3)	($0.3)	($0.4)	($1.9)	($1.5)	($1.0)	$1.0
Pre-Tax Income	($5.9)	($6.8)	($4.5)	($3.6)	($2.4)	($1.7)	($12.3)	$14.5	$30.2	$28.5
Taxes & Other	$0	($1.2)	$0	$0	$0	$0	$0	$0	$4.5	$8.6
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5%*	*15%*	*30%*
Net Income	($5.9)	($5.6)	($4.5)	($3.6)	($2.4)	($1.7)	($12.3)	$14.5	$25.7	$20.0
Net Margin	*0%*	*0.0%*	-	-	-	-	*-195.2%*	*52.5%*	*56.8%*	*47.5%*
Reported EPS	**($0.10)**	**($0.09)**	**($0.08)**	**($0.06)**	**($0.04)**	**($0.03)**	**($0.21)**	**$0.23**	**$0.40**	**$0.30**
YOY Growth	-	*-6.2%*	-	-	-	-	*119.1%*	*-212.2%*	*72.9%*	*-24.6%*
Weight Ave. Shares Out	58.5	59.2	59.2	59.3	59.3	59.5	59.3	62.5	64.0	66.0

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

© Copyright 2011, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

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

ZIR or Zacks SCR Analysts do not hold or trade securities in the issuers which they cover. Each analyst has full discretion on the rating and price target based on their 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 non-investment banking services. 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 blog.

ZIR and Zacks SCR do not make a market in any security nor do they act as dealers in securities. Zacks SCR has never received compensation for investment banking services on the small-cap universe. Zacks SCR does not expect received compensation for investment banking services on the small-cap universe. 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. Non-investment banking services include investor relations services and software, financial database analysis, advertising services, brokerage services, advisory services, investment research, and investment management.

Additional information is available upon request. Zacks SCR reports are based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the 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. Reports are not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks SCR uses the following rating system for the securities it covers. 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 of Zacks Ratings is as follows on the 1030 companies covered: Buy/Outperform- 14.3%, Hold/Neutral- 79.3%, Sell/Underperform – 5.1%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2011, Zacks Investment Research. All Rights Reserved.