Zacks Small-Cap Research

November 7, 2012
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Trius Therapeutics (TSRX-NASDAQ)

TSRX: Buy Trius Ahead Of Pivotal Phase 3 Data Expected Early 2013…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/24/2011
Current Price (11/07/12)	$5.14
Target Price	**$12.00**

UPDATE

We see Trius as a company with a dramatically lowered risk profile from late 2011. Data from the first phase 3 trial was excellent and second phase 3 trial should offer up similar results. The finances are strong, with $70.7 million in cash on hand at the end of the third quarter 2012.

We see meaningful market share gains for tedizolid over the three market leading products, Zyvox, Cubicin, and Tygacil once approved. The current market cap of only ~$200 million vastly undervalues the story in our view. We think the stock is worth $12 per share based on discounted cash flow (DCF) analysis.

Our U.S. peak sales forecast is $400 million. Our global peak sales forecast is $750 million.

SUMMARY DATA

52-Week High	**$7.85**
52-Week Low	**$4.80**
One-Year Return (%)	**-23.76**
Beta	**0.33**
Average Daily Volume (sh)	**90,584**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$209**
Short Interest Ratio (days)	**6.70**
Institutional Ownership (%)	**45**
Insider Ownership (%)	**30**
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-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	2.7 A	2.9 A	30.4 A	5.0 A	41.0 A
2012	9.8 A	6.2 A	6.0 A	6.0 E	28.0 E
2013					25.0 E
2014					5.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.43 A	-$0.40 A	$0.49 E	-$0.44 A	-$0.69 A
2012	-$0.22 A	-$0.37 A	$0.46 A	-$0.40 E	-$1.45 E
2013					-$1.02 E
2014					-$1.23 E

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WHAT'S NEW

Recent Financial Results

On November 5, Trius Therapeutics reported financial results for the third quarter 2012. Total revenues in the quarter were $6.0 million, and consisted of $2.3 million in contract research from the company's NIAID and DTRA grants and $3.7 million collaborative and licensing fees from Bayer Pharma AG, the company's partner in Asia/Pacific market for tedizolid phosphate. For the first nine months of 2012, Trius recognized $14.5 million in revenues from Bayer, which included a $5.0 million milestone payment in the first quarter for the successful completion of the TR701-112 phase 3 study.

Net loss in the third quarter totaled $17.7 million, or 46 cents per share. Research and Development expenses in the quarter totaled $19.3 million. S&GA expense totaled $4.4 million. Both line items came in higher than expected. Management noted pre-commercialization activities and higher personnel costs associated with increasing headcount leading to the uptick in operating expenses during the quarter. As of early November, enrollment in the second phase 3 trial with tedizolid, TR701-113, continues on plan with data expected in early 2013.

…Solid Cash Position…

Trius exited the third quarter 2012 with $70.9 million in cash and investments. We remind investors that on August 31, 2012, the company entered into a common stock purchase agreement (CSPA) with Terrapin Opportunity, L.P., pursuant to which Trius may, from time to time sell Terrapin shares of common stock. Through September 30, 2012, Trius did not sell any stock pursuant to the CSPA.

However, on October 10, 2012, Trius sold 612,133 shares of common stock under the CSPA to raise net proceeds of $3.4 million. Taking this into account, and factoring in operating burn in the fourth quarter 2012, we now see cash at the end of the year at just above $60 million. We find this to be sufficient to fund operations throughout 2013. With data from -113 expected in early 2013 we do not see a need for additional financings prior to the release of the data. We believe that Trius even has the funds necessary to initiate a third phase 3 trial in HAP/VAP (lung infection) during the first half of 2013. We remind investors that management is also planning a fourth phase 3 trial in bacteremia (systemic infections) in 2014.

Fundamentals Remain Strong

We believe fundamentals at Trius remain solid. We see the development of tedizolid, current in its second phase 3 trial, as low risk. Data from the first phase 3 trial met all primary and secondary endpoints. Management has present impressive safety and efficacy data from this trial at recent medical meetings, including the IDWeek2012 meeting in October and ICAAC in September. We highlight some of this data below.

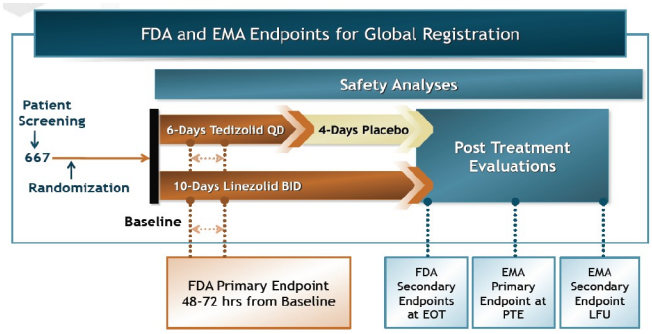
The company has secured a strong partner for the Asia/Pacific and emerging markets in Bayer Pharma AG. We believe Bayer is keen on licensing the European rights to tedizolid, although with the data from -113 now roughly two months away, we are pushing back our expectations for a deal to the second quarter 2013.

Finally, Trius is well funded. We model over $60 million in cash on hand at the end of the year. We see fair-value at $12 per share based on our 10-year DCF model. We believe Trius is an attractive take-over candidate for a specialty pharmaceutical company looking to enhance its late-stage anti-infectant pipeline. We would be aggressive buyers of the stock at this level.

INVESTMENT THESIS

1st Phase 3 Trial Meets Primary & Secondary Endpoints

On December 19, 2011, Trius Therapeutics announced results from the company's 1st phase 3 trial (TR701-112) studying 200mg once-daily oral tedizolid for 6 days versus 600mg twice-daily oral linezolid (Pfizer's Zyvox) for 10 days in patients with acute bacterial skin and skin structure infections (ABSSSI).



The trial was a non-inferiority design (90% power to detect a 10% non-inferiority margin between the two arms). The trial enrolled a total of 667 patients across sites in North America.

The primary endpoint was cessation of lesion spread and resolution of fever at 48-72 hours after initiation of study drug on an intent-to-treat (ITT) analysis. There were also key secondary endpoints, including sustained clinical response at end-of-treatment (EOT) in the ITT and clinically evaluable (CE) populations and an investigator's assessment of clinical success in the ITT and CE populations.

Full data from this trial was presented in poster form at the 52nd annual Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC) in September 2012. The primary endpoint was response rate, defined as cessation of spread and absence of fever at 48-72 hours. The main cause of clinical failure was missing or out of window temperature measurements. Based on these results, tedizolid was non-inferior to linezolid for the primary efficacy analysis of early clinical response.

Response	Tedizolid Phosphate N=332	Linezolid N=335
Responder	264 (79.5)	266 (79.4)
Nonresponder or indeterminate	68 (20.5)	69 (20.6)
Nonresponder	27 (8.1)	35 (10.4)
Indeterminate	41 (12.3)	34 (10.1)

A number of secondary analyses of the data were performed. These include looking at the responder analysis solely based on a greater than 20% decrease in lesion area at 48-72 hours, as well as investigator assessments of clinical success at the post-therapy evaluation (PTE) based on the ITT and CE populations.

Response	Tedizolid Phosphate N=332	Linezolid N=335
Responder	259 (78.0)	255 (76.1)
ITT	322	335
Clinical success	284 (85.5)	288 (86.0)
CE-PTE	279	280
Clinical success	264 (94.6)	267 (95.4)

There is a greater than 80% concordance between the primary outcome at 48-72 hours and the investigator assessments of clinical response at PTE. Considering the majority of clinical failure was due to missing or incomplete temperature data, Trius performed a secondary analysis of the data excluding assessment of fever. According to management, tedizolid offers up numerically better results on the cessation of lesions endpoint – approximately 87.5% vs. 85.4%. Both drugs lost efficacy points due to missing temperature data. It becomes difficult to prove in a clinical setting the rapid onset of efficacy when clinicians are not always following the exact FDA guidelines with respect for registration of a new drug application. Missing temperature data or failures at 48-72 hours on temperature were carried forward to the end-of-treatment. This protocol has been rectified for the second phase 3 trial (TR701-113) currently enrolling patients. Additionally, management expects this will be the finalized endpoint for approval based on FNIH recommendations to the FDA (ABSSSI Docket ID:FDA-2010D-0433).

The data above look good. As noted in our previous reports, management did not expect tedizolid to achieve superiority to linezolid. To achieve superiority, tedizolid drug would have had to have posted a primary endpoint >7% versus linezolid. Truth be told, linezolid is a highly effective drug. Pfizer would not have sold $1.3 billion of Zyvox in 2011 if the drug didn't work. We note the rates of methicillin-resistance *Staphylococcus aureus* (MRSA) infection and outcomes were similar between both arms at around 42-43%.

We think these data are consistent with the clinical profile of the drug demonstrated in early trials. That being said, the safety and tolerability profile of tedizolid surprised to the upside.

- ✓ Any drug related treatment emergent adverse events (TEAE) were higher for the linezolid group (31.0%) vs. tedizolid (24.2%). Separation between the two drugs was primary the result of improved GI tolerability for tedizolid. Gastrointestinal disorders, which include nausea, vomiting, and diarrhea, were statistically significant in favor of tedizolid (16.3%) vs. linezolid (24.4%).

TEAEs, System Organ Class	Tedizolid phosphate N=331 n (%)	Linezoliid N=335 n (%)
Gastrointestinal Disorders*	54 (16.3)	85 (25.4)
Diarrhoea	15 (4.5)	18 (5.4)
Dyspepsia	2 (0.6)	7 (2.1)
Nausea	28 (8.5)	45 (13.4)
Vomiting	9 (2.7)	20 (6.0)

- ✓ Tedizolid also had less of a detrimental effect on platelet count (-9.2% for tedizolid vs. -14.9% for linezolid), including percent consider abnormally low (<75% LLN) at 2.3% for tedizolid vs. 4.9% for linezolid. The separation becomes statistically significant if the data is adjusted for patients with abnormal or missing baseline platelet counts.

Platelet Data	Tedizolid phosphate n (%)	Linezoliid n (%)	p-value
Subjects with any baseline platelet count and the worst (lowest) post-baseline value	N = 304	N = 308	
Below LLN	28 (9.2)	46 (14.9)	0.035
Substantially abnormal	7 (2.3)	15 (4.9)	0.127
Excluding subjects with an abnormal or missing baseline platelet count, values at Study Days 11-13	N = 259	N = 247	
Below LLN	8 (3.1)	19 (7.7)	0.028
Substantially abnormal	1 (0.4)	7 (2.8)	0.034
Including subjects with an abnormal baseline value and excluding subjects with a missing baseline platelet count, values at Study Days 11-13	N = 268	N = 266	
Below LLN	9 (3.4)	30 (11.3)	0.0004
Substantially abnormal	2 (0.7)	12 (4.5)	0.0065

- ✓ The data suggest that tedizolid also had less of a detrimental effect liver function. ALT above the normal limit was 27.7% for tedizolid at EOT versus 33.0% for linezolid.

Hepatic Laboratory Values	Tedizolid phosphate n (%)	Linezoliid n (%)
ALT	N = 314	N = 312
Above ULN	87 (27.7)	103 (33.0)
Substantially abnormal	13 (4.1)	11 (3.5)
AST	N = 312	N = 312
Above ULN	80 (25.6)	91 (29.2)
Substantially abnormal	8 (2.6)	10 (3.2)
Alkaline phosphatase	N = 317	N = 317
Above ULN	51 (16.1)	47 (14.8)
Substantially abnormal	0	0
Total bilirubin	N = 317	N = 316
Above ULN	3 (0.9)	9 (2.8)
Substantially abnormal	0	0

- ✓ One final assessment management made on the -112 data was based on the current European regulatory guidelines. Currently, the EMA assesses utility based on the clinical cure at days 17-21. Tedizolid was numerically superior to linezolid based on the EMA endpoint, 98% vs. 91%. We believe this data plays nicely into the company's strategy to partner the drug in Europe in 2013.

Besides better tolerability, we noted the significant administrative and convenience advantages of tedizolid versus linezolid, including a shorter course of treatment (6 days vs. 10 days), once-daily dosing, and bioequivalence between the oral and IV dose.

We think tedizolid can gain market share from linezolid based on these advantages. With the above marketing advantages on safety and convenience and a superior efficacy claim, we think tedizolid could have best-in-class. Based on the top-line data from -112, we still think tedizolid will be a very nice drug for Trius. Paramount is that Trius gets the drug on the market before Zyvox loses patent exclusivity in mid-2015.

…Second Phase 3 Ongoing…

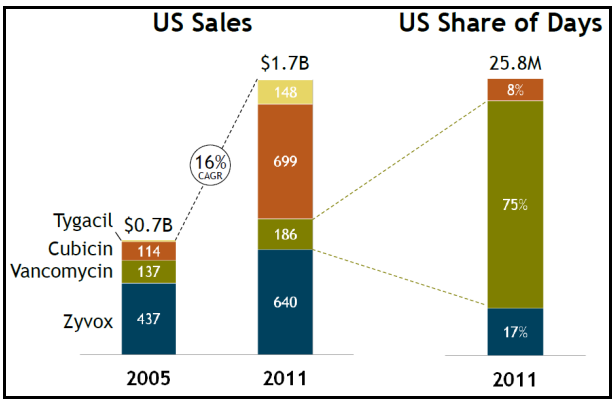
We remind investors that Trius is also testing tedizolid in a second phase 3 trial, TR701-113, also under a U.S. FDA SPA. TR701-113 is an IV-to-Oral step-down trial that will compare the efficacy and safety of 200mg QD tedizolid for 6 days to 600mg BID linezolid (Zyvox) for 10 days. All patients will be initiated on IV dosage form for a minimum of one day and be transitioned to the oral dose form at the discretion of the clinical investigator. We note that having both an IV and oral dosage formulation is a key differentiator to Cubist's Cubicin (daptomycin). We expect data from this program in early 2013.

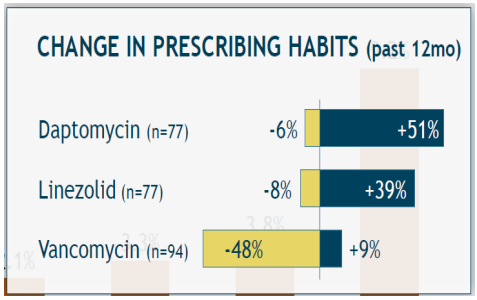
Trius is also planning a third phase 3 trial in HAP/VAP (lung infection) to start sometime during the first half of 2013, and a fourth phase 3 trial in bacteremia (systemic infections) in 2014.

Commercial Potential Is Very Attractive

We see a significant commercial potential for tedizolid in the U.S. If the second phase 3 program goes as we expect, the drug has peak sales in the $300 million to $350 million range in North America. The current market is dominated by vancomycin and linezolid. The therapeutic window on both is closing. Key for Trius is to gain the cleanest and widest label possible. Expanding the indications into HAP/VAP, pneumonia, and bacteremia provide meaningful upside to our forecast.

This is clearly a large market. U.S. sales for Zyvox, Cubicin, Tygacil, and generic vancomycin eclipsed $1.7 billion in 2011. Vancomycin prescriptions grew by 6% CAGR between 2005 and 2010. Yet, despite the presence of generic vancomycin, branded sales of Zyvox, Cubicin, and Tygacil grew by 20% CAGR. The market is shifting to more effective drugs, and price is becoming less of a factor. Prescribing habits are changing thanks to growing MRSA resistance to vancomycin. Use of Cubicin and Zyvox is up 40-50% over the past twelve months versus a near 50% decrease in use for generic vancomycin.

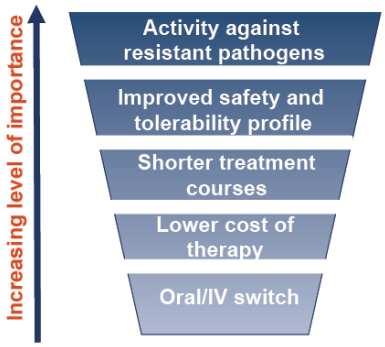




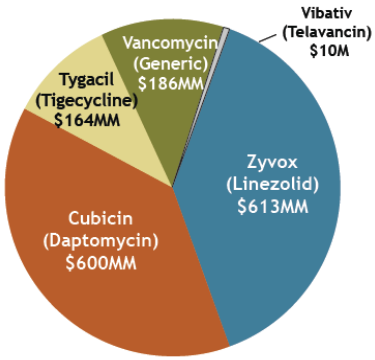
Initial market research conducted by management on formulary acceptance shows that with a non-inferior profile to Zyvox, tedizolid will see broad (~90%) Tier-2 coverage at parity pricing per course of treatment (~$1,500) to Zyvox. This includes a range of indications, including skin, HAP/VAP, Bacteremia, and MRSA. We estimate 1% market share of the U.S. hospital market is $50 million in sales, and 1% of the outpatient market is $25 million in sales.

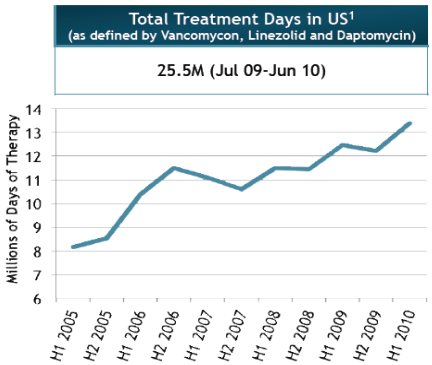
Trius held an R&D day in early December 2011 that offered perspective from two leading physicians with significant experience in treating patients with MRSA: Dr. Ralph Corey, Profession or Medicine and Infectious disease at Duke University and Dr. Jeff Kingsley, CEO of the Southeast Regional Research Group. Both doctors concluded that despite the availability of generic vancomycin and expensive branded products such as Zyvox, Cubicin, and Tygacil, a void remained in the market for a highly effective drug that met all the requirements for success.

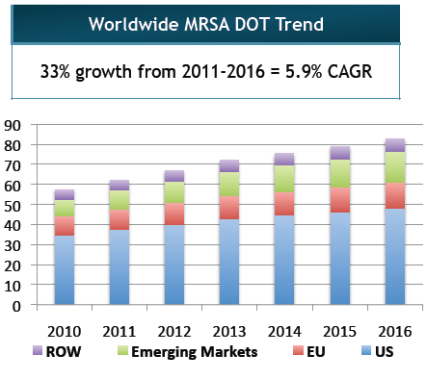
Based on data presented by management on the clinical and non-clinical history of tedizolid, we see the drug is poised to be "Best-in-Class" with a full label.



…A Large And Growing Market…







Based on current timelines, we are expecting a new drug application (NDA) around the middle of 2013 in ABSSSI, with FDA approval in 2014. Additional applications for HAP/VAP, pneumonia, and bacteremia should follow in 2014 and beyond. The biggest near-term catalyst for the shares is a deal for the European market, where we are hoping can be completed sometime during the first half of 2013. We think Bayer Pharma AG is the likely partner, but with a solid cash position we believe Trius feels little pressure to get a deal done until all roads have been explored.

Trius currently owns unencumbered rights to develop, commercialize or separately partner in the U.S., Canada, and the EU. We note the company has reported entering into confidential disclosure agreements (CDAs) with several interested parties. That being said, Bayer would be an outstanding commercial partner for Trius in any market. Bayer has expertise in anti-infectants including Cipro and Avalox, and Bayer has the financial strength and experience to launch Tedizolid in Asia, including China, and Europe, as well as potential emerging markets across the Africa, Latin America, and the Middle East. We expect Bayer to commence clinical work in China / Japan shortly. We remind investors that Bayer is currently paying for 25% of the global development costs on tedizolid.

…Key Advantages vs. Both Zyvox & Cubicin…

	Zyvox (linezolid)	Cubicin (daptomycin)	Generic (vancomycin)	Tedizolid
IV & Oral Formulation	YES	NO	NO	YES
Once Daily Dosing	NO	YES	NO	YES
Short Course of Therapy	NO	NO	NO	YES
Skin Infections	YES	YES	YES	YES
Active In Lung Infections	YES	NO	NO	YES
Bacteremia	NO	YES	YES	YES
Superior Tolerability	NO	NO	NO	YES

PROJECTED FINANCIALS

Trius Therapeutics, Inc.
Income Statement

	2010 A	2011 A	Q1 A	Q2 A	Q3 A	Q4 E	2012 E	2013 E	2014 E	2015 E
Tedizolid (N.A. Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$15.4
YOY Growth	-	-	-	-	-	-	-	-	-	-
Tedizolid (EU Royalties)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$2.6
YOY Growth	-	-	-	-	-	-	-	-	-	-
Tedizolid (Asia/EM Royalties)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$2.6
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Tedizolid Revs	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$21**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Contracts & Collaborations	**$8.0**	**$41.0**	**$9.8**	**$6.2**	**$6.0**	**$6.0**	**$28.0**	**$25.0**	**$5.0**	**$15.0**
YOY Growth	-	*100.0%*	-	-	-	-	*-31.7%*	*-10.8%*	*-80.0%*	*200.0%*
Total Revenues	**$8.0**	**$41.0**	**$9.8**	**$6.2**	**$6.0**	**$6.0**	**$28.0**	**$25.0**	**$5.0**	**$35.6**
YOY Growth	*60.1%*	*100.0%*	-	-	-	-	*-31.7%*	*-10.8%*	*-80.0%*	*612.0%*
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0	$1.5
Product Gross Margin	*0.0%*	*0.0%*	-	-	-	-	*0%*	*0%*	*0%*	*0%*
R&D	$23.3	$49.5	$16.8	$16.4	$19.3	$17.5	$70.1	$50.0	$40.0	$40.0
% R&D	-	-	-	-	-	-	*249.9%*	*200.0%*	*800.0%*	*112.4%*
SG&A	$5.4	$11.3	$3.0	$3.3	$4.4	$4.0	$14.7	$18.0	$20.0	$30.0
% SG&A	-	*27.6%*	-	-	-	-	*52.6%*	*72.0%*	*400.0%*	*84.4%*
Operating Income	($20.7)	($19.8)	($10.0)	($13.5)	($17.8)	($15.5)	($56.8)	($43.0)	($55.0)	($36.0)
Operating Margin	*0.0%*	*-48.4%*	-	-	-	-	*-202.5%*	*-172.0%*	*-1100.0%*	*-101.1%*
Interest & Other Income	($3.2)	$1.6	$2.4	($0.9)	$0.1	($0.1)	$1.5	($0.4)	($0.2)	($0.2)
Pre-Tax Income	($23.9)	($18.3)	($7.6)	($14.4)	($17.7)	($15.6)	($55.3)	($43.4)	($55.2)	($36.2)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($23.9)	($18.3)	($7.6)	($14.4)	($17.7)	($15.6)	($55.3)	($43.4)	($55.2)	($36.2)
Net Margin	*0.0%*	*-44.5%*	-	-	-	-	*-197.3%*	*-173.6%*	*-1104.0%*	*-101.7%*
Reported EPS	**($2.36)**	**($0.69)**	**($0.22)**	**($0.37)**	**($0.46)**	**($0.40)**	**($1.45)**	**($1.02)**	**($1.23)**	**($0.76)**
YOY Growth	*-92.4%*	*-70.9%*	-	-	-	-	*111.0%*	*-29.7%*	*20.1%*	*-37.9%*
Basic Shares Outstanding	10.1	26.5	35.2	38.7	38.8	39.5	38.0	42.5	45.0	47.5

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

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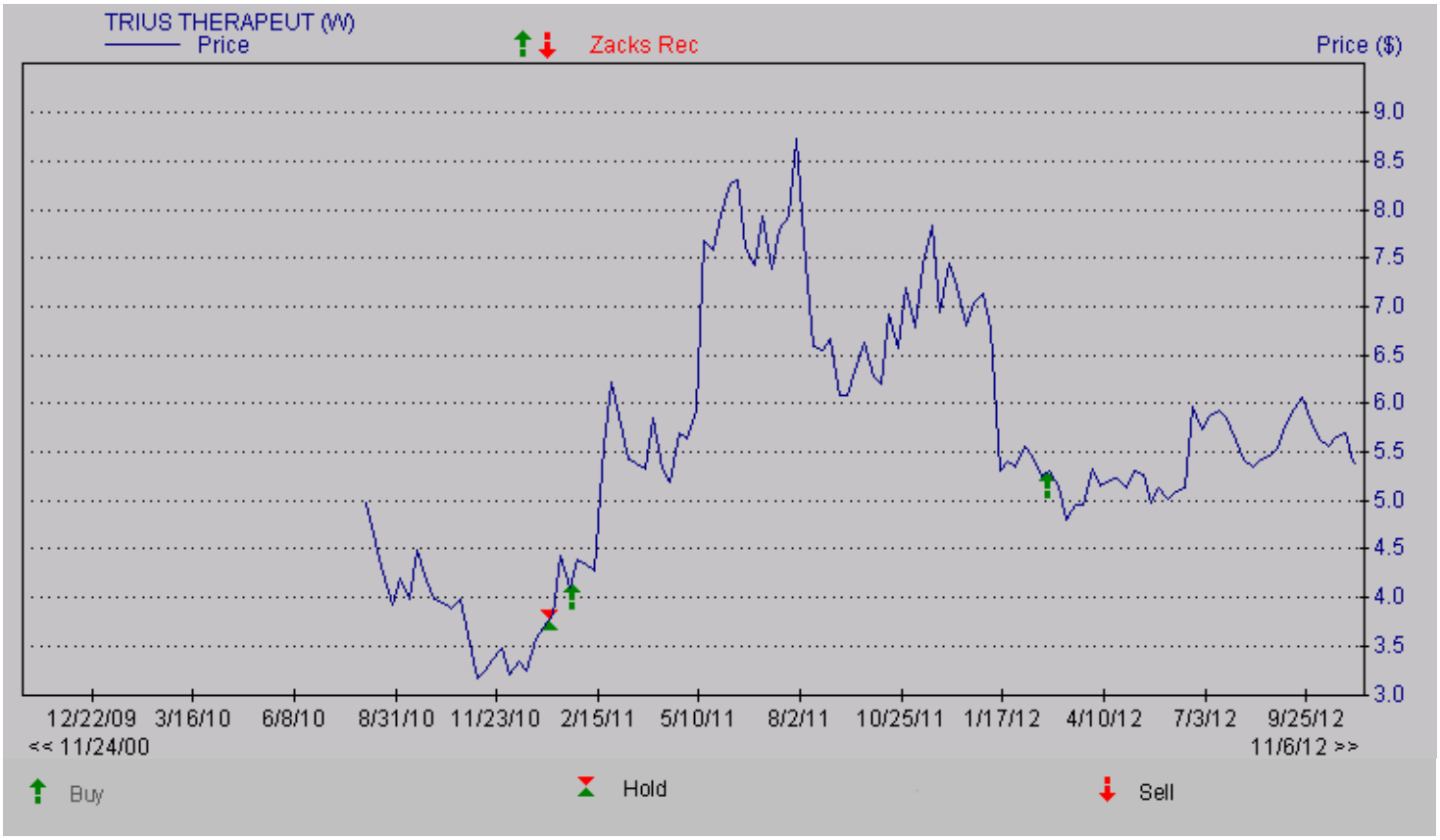
HISTORICAL ZACKS RECOMMENDATIONS



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