Zacks Small-Cap Research

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Trius Therapeutics (TSRX-NASDAQ)

TSRX: Time To 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 (08/07/12)	$5.45
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 $83.8 million in cash on hand at the end of the second 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 ~$212 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	**$4.80**
One-Year Return (%)	**-9.74**
Beta	**0.27**
Average Daily Volume (sh)	**169,053**
Shares Outstanding (mil)	**39**
Market Capitalization ($mil)	**$212**
Short Interest Ratio (days)	**4.51**
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	4.5 E	5.0 E	25.6 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	$0.39 E	-$0.40 E	-$1.39 E
2013					-$0.72 E
2014					-$1.10 E

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WHAT'S NEW

Recent Financial Results

On August 6, 2012, Trius Therapeutics reported financial results for the second quarter 2012. Total revenues in the quarter were $6.2 million, and consisted of $2.2 million in contract research from the company's NIAID and DTRA grants and $4.0 million collaborative and licensing fees from Bayer Pharma AG, the company's partner in Asia/Pacific market for tedizolid phosphate. For the first six months of 2012, Trius recognized $10.8 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 quarter totaled $14.4 million, or 37 cents per share. Research and Development expenses in the quarter totaled $16.4 million, right in-line with our estimate. We note enrollment in the second phase 3 trial with tedizolid, TR701-113, continues on plan with data expected in early 2013. S&GA expense was slightly higher than our expectations in the quarter, coming in at $3.3 million.

…Solid Cash Position…

Trius exited the second quarter 2012 with $83.8 million in cash and investments. The cash position was bolstered in January 2012 through an underwritten public offering of approximately 9.9 million shares of common stock at a price of $5.25 per share, for net proceeds after fees of $48.4 million. We find this to be sufficient to fund operations well into the future, including the ongoing second phase 3 trial (TR701-113) and a planned HAP/VAP (lung infection) phase 3 trial planned for the first half of 2013. We remind investors that management is also planning a fourth phase 3 trial in bacteremia (systemic infections) in 2014.

…EU Partnership Remains Biggest Catalyst Near-term…

Trius is in talks with potential European partners on tedizolid. We suspect that Bayer Pharma AG is the likely eventual European partner for the company, but the solid cash position allows the company to continue to entertain offers from other companies.

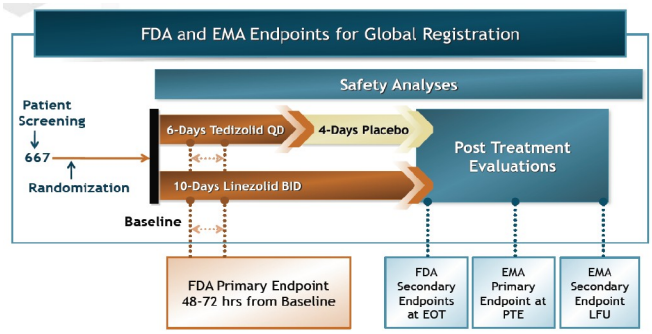
Fundamentals Remain Strong

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. 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 later this year. Finally, Trius is well funded, with $83.8 million in cash on hand at the end of the second quarter 2012. 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.

…Top-Line Data…

ABSSSI	Tedizolid	Linezolid
Dosing Regimen	200mg QD For 6 Days	600mg BID For 10 Days
Primary Endpoint		
Cessation of Spread & Absence of Fever at 48-72 hrs	79.5%	79.4%
Secondary Endpoints		
Sustained Response (Day 10) – ITT	69.3%	71.9%
Sustained Response (Day 10) – CE	80.2%	81.1%
Investigator Assessment (Day 7-14) – ITT	85.5%	86.0%
Investigator Assessment (Day 7-14) – CE	94.6%	95.4%
>20% Decrease in Lesion Area (48-72 hrs)	78.0%	76.1%
Safety & Tolerability		
Treatment Emergent Adverse Event (TEAE)	40.8%	43.3%
Any Drug Related TEAE	24.2%	31.0%
Gastrointestinal Disorders	16.3%	24.4%

…Quick Analysis…

The data above look very 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.

We are surprised that the primary outcome was so close, but we note that the primary endpoint is a composite of both cessation of lesions and absence in fever. According to management, tedizolid offers up numerically better results on the cessation of lesions endpoint – approximately 87% vs. 85%. 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.

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%).
- ✓ Gastrointestinal disorders, which include nausea, vomiting, and diarrhea, were statistically significant in favor of tedizolid (16.3%) vs. linezolid (24.4%).
- ✓ 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.

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 is 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.

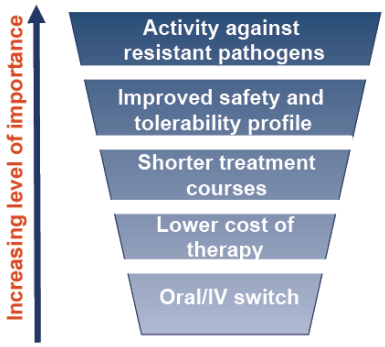
…Commercial Potential Is Very Attractive…

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 $1.5 billion in 2010. 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.

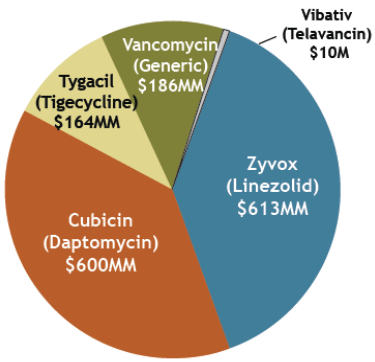
In fact, initial market research conducted by management on formulary acceptance shows that with a non-inferior profile to Zyvox, tedizolid will see broad (~90%) Tier-2 coverage at parity pricing per course of treatment (roughly $1,500) to Zyvox. This includes a range of indications, including skin, HAP/VAP, Bacteremia, and MRSA.

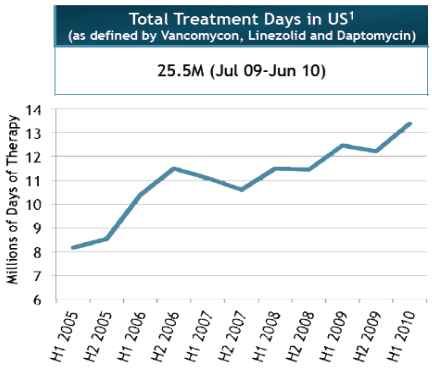
Trius held an R&D day in early December 2011 that offered perspective from two leading physicians with significant experience in treating patients with MRSA: Dr. Ralph Corey, Profession or Medicine and Infectious disease at Duke University and Dr. Jeff Kingsley, CEO of the Southeast Regional Research 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.

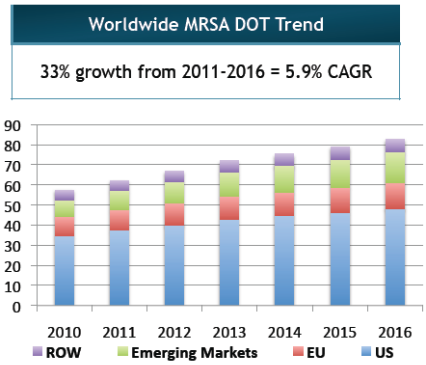


Based on data presented by management on the clinical and non-clinical history of tedizolid, we see the drug is poised to be "Best-in-Class" with a full label.

…A Large And Growing Market…







Based on current timelines, we are expecting a new drug application (NDA) around the middle of 2013in 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, perhaps to be completed sometime later in 2012. We think Bayer Pharma AG is the likely partner, but with a solid cash position we believe Trius feels to 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

IND Work Initiated On Gyrase

In December 2011, Trius initiated IND-enabling studies for a Gyrase-B development candidate. This work continues as of early August 2012. Management has noted this candidate has potent activity against Gram-negative bacterial pathogens, including multi-drug resistant strains of *E. coli, Klebsiella, Acinetobacter and Pseudomonas*. Management plans to enter phase 1 clinical testing in 2013.

Work with Gyrase-B is being funded through phase 1 by a $28 million NIAID contract. The scope of the contract includes preclinical, nonclinical and clinical IND- and/or NDA-enabling activities. Pursuant to this NIAID contract, Trius retains worldwide non-exclusive royalty-free license rights to the drug.

PROJECTED FINANCIALS

Trius Therapeutics, Inc.
Income Statement

	2010 A	2011 A	Q1 A	Q2 A	Q3 E	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**	**$4.5**	**$5.0**	**$25.6**	**$25.0**	**$5.0**	**$15.0**
YOY Growth	-	*100.0%*	-	-	-	-	*-37.7%*	*-2.2%*	*-80.0%*	*200.0%*
Total Revenues	**$8.0**	**$41.0**	**$9.8**	**$6.2**	**$4.5**	**$5.0**	**$25.6**	**$25.0**	**$5.0**	**$35.6**
YOY Growth	*60.1%*	*100.0%*	-	-	-	-	*-37.7%*	*-2.2%*	*-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	$16.5	$17.0	$66.7	$40.0	$35.0	$30.0
% R&D	-	-	-	-	-	-	*261.1%*	*160.0%*	*700.0%*	*84.3%*
SG&A	$5.4	$11.3	$3.0	$3.3	$3.2	$3.3	$12.8	$13.5	$16.0	$30.0
% SG&A	-	*27.6%*	-	-	-	-	*50.1%*	*54.0%*	*320.0%*	*84.4%*
Operating Income	($20.7)	($19.8)	($10.0)	($13.5)	($15.2)	($15.3)	($54.0)	($28.5)	($46.0)	($26.0)
Operating Margin	*0.0%*	*-48.4%*	-	-	-	-	*-211.2%*	*-114.0%*	*-920.0%*	*-73.0%*
Interest & Other Income	($3.2)	$1.6	$2.4	($0.9)	($0.1)	($0.1)	$1.3	($0.4)	($0.2)	($0.2)
Pre-Tax Income	($23.9)	($18.3)	($7.6)	($14.4)	($15.3)	($15.4)	($52.7)	($28.9)	($46.2)	($26.2)
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)	($15.3)	($15.4)	($52.7)	($28.9)	($46.2)	($26.2)
Net Margin	*0.0%*	*-44.5%*	-	-	-	-	*-206.3%*	*-115.6%*	*-924.0%*	*-73.6%*
Reported EPS	**($2.36)**	**($0.69)**	**($0.22)**	**($0.37)**	**($0.39)**	**($0.40)**	**($1.39)**	**($0.72)**	**($1.10)**	**($0.60)**
YOY Growth	*-92.4%*	*-70.9%*	-	-	-	-	*101.7%*	*-48.0%*	*52.2%*	*-45.9%*
Basic Shares Outstanding	10.1	26.5	35.2	38.7	38.8	39.0	37.9	40.0	42.0	44.0

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

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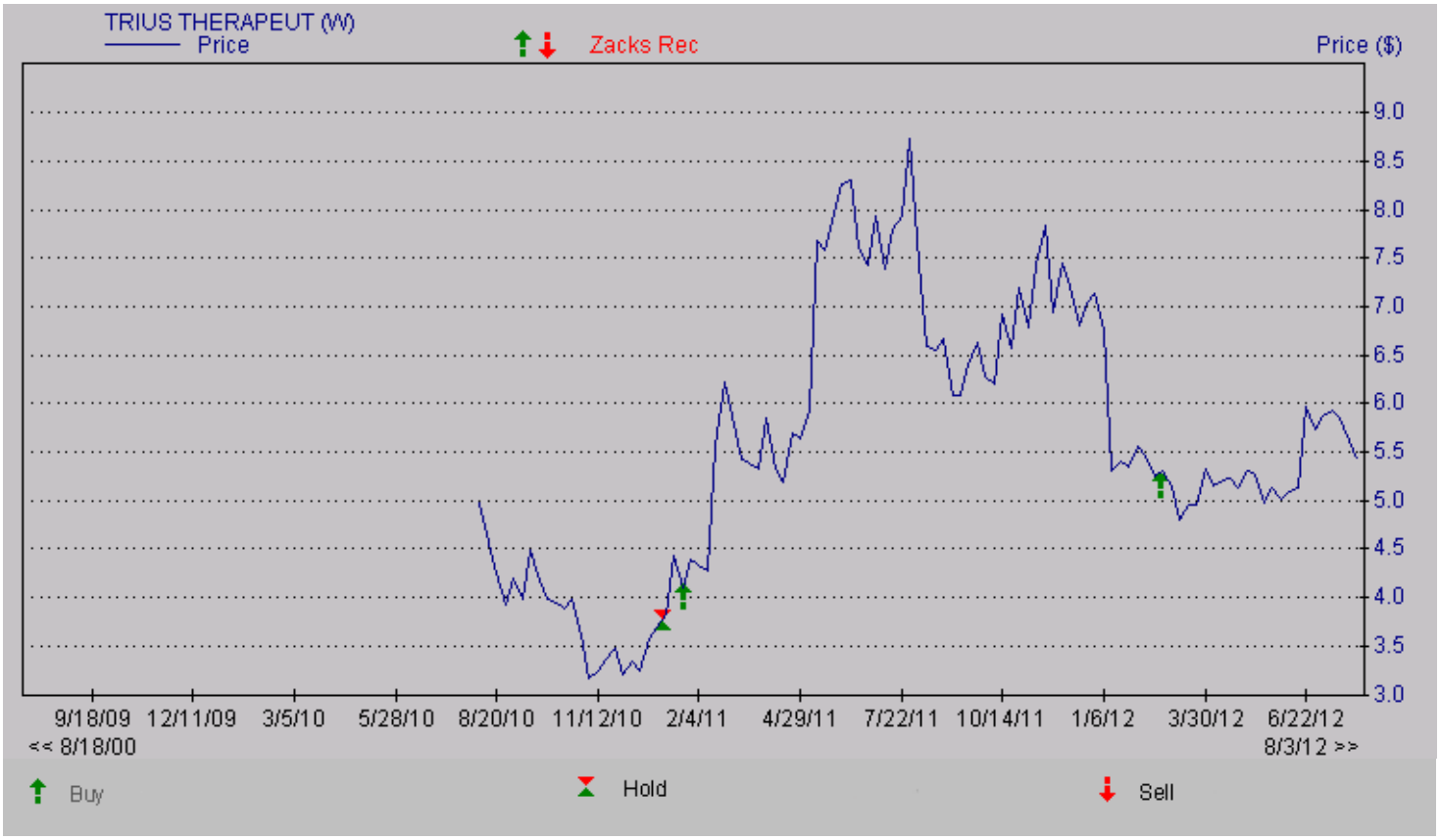

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