Zacks Small-Cap Research

March 25, 2013
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Trius Therapeutics (TSRX-NASDAQ)

TSRX: ESTABLISH-2 Confirms Tedizolid Efficacy, NDA Expected 2H-2013…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/24/2011
Current Price (03/25/13)	$6.89
Target Price	**$12.00**

UPDATE

This morning Trius reported top-line results from its second phase 3 study, ESTABLISH-2, with antibacterial agent, tedizolid phosphate. The data show the drug to be non-inferior to Pfizer's $1.35 billion drug Zyvox (linezolid), with several advantages in both dosing and safety and tolerability. We expect full data from the trial at the ICAAC conference in September 2013, and the U.S. NDA filing in September or October 2013.

The current market cap of only ~$350 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	**$7.30**
52-Week Low	**$4.45**
One-Year Return (%)	**23.21**
Beta	**0.21**
Average Daily Volume (sh)	**562,083**
Shares Outstanding (mil)	**45**
Market Capitalization ($mil)	**$280**
Short Interest Ratio (days)	**2.42**
Institutional Ownership (%)	**52**
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 2013 Estimate	**N/A**
P/E using 2014 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)
2012	9.8 A	6.2 A	6.0 A	5.2 A	27.2 A
2013	5.0 E	5.0 E	5.0 E	5.0 E	20.0 E
2014					20.0 E
2015					40.6 E

Earnings per Share

(EPS is operating earnings before non-recurring items)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.22 A	-$0.37 A	$0.46 A	-$0.36 A	-$1.42 A
2013	-$0.34 E	-$0.32 E	$0.32 E	-$0.33 E	-$1.28 E
2014					-$1.15 E
2015					-$0.60 E

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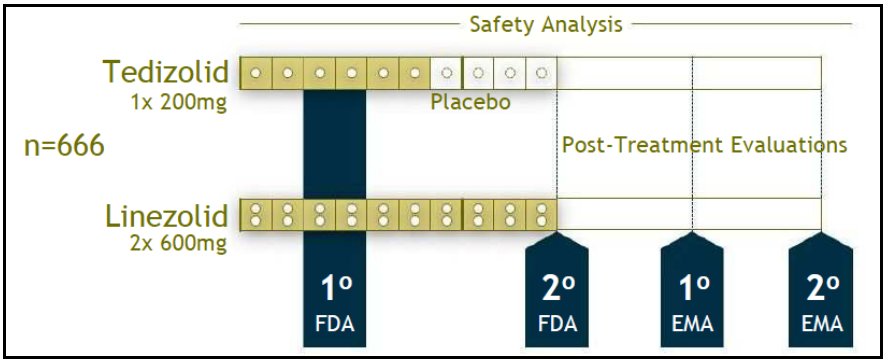
WHAT'S NEW

ESTABLISH-2 Hits!

On March 25, 2013, Trius Therapeutics announced top-line results from the ESTABLISH-2 phase 3 clinical trial of tedizolid phosphate for the treatment of acute bacterial skin and skin structure infections (ABSSSI), including methicillin resistant *Staphylococcus aureus* (MRSA). Results show that EASTABLISH-2, an intravenous (IV) to oral transition study, met the primary and key secondary endpoints for both U.S. U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) regulatory guidelines for ABSSSI, and confirm the previous data from the ESTABLISH-1 all oral dose phase 3 trial.

ESTABLISH-2 was conducted at 95 sites in North and South America, Europe, Australia, New Zealand and South Africa. The randomized, double-blind study pitted 200 mg of tedizolid once daily for six days (plus four days of placebo) vs. 600 mg of linezolid, sold as Pfizer's Zyvox, twice daily for 10 days. Patients initially received the IV dosage form of either tedizolid or linezolid with the option to switch to the respective oral dosage forms at the discretion of the clinical investigator on or after the second day of treatment.



The primary endpoint was non-inferiority (10% NI margin) to linezolid as measured by a 20% or greater reduction in lesion area at 48 to 72 hours after the first infusion of study drug. Tedizolid also met all secondary efficacy endpoints measured at both the end of therapy and post treatment evaluations. Top-line results on an intent-to-treat (ITT) analysis from the trial are presented below:

EASTABLISH-2	Tedizolid 200mg 6 Days QD (n=332)	Linezolid 600mg 10 Days BID (n=334)	Comments
Primary Endpoint			
>20% Decrease from Baseline in Lesion Area at 48-72 hours	**85.2%**	**82.6%**	**+2.6 (-3.0 to 8.2) 95% CI**
Secondary Endpoint			
Sustained Clinical Response at End of Therapy	**87.0%**	**88.0%**	
Investigators Assessment of Clinical Response at 7-14 Days at End of Therapy	**88.0%**	**87.7%**	**Primary Endpoint For EU-MAA Filing**
Cessation of Spread and Absence of Fever at 48-72 hours	**85.8%**	**81.4%**	**Sensitivity Analysis / 2010 FDA Guidelines**
Safety & Tolerability			
Treatment Emergent Adverse Events	**45.3%**	**43.7%**	
Drug Related Averse Events	**20.5%**	**24.8%**	
Gastrointestinal Adverse Events	**16.0%**	**20.5%**	**Consistent with ESTABLISH-1 Results**
Platelet Level Below Normal	**13.5%**	**13.0%**	**No difference, unlike EST-1.**
Discontinuations Rate	**5.4%**	**8.4%**	

The top-line data from the ESTABLISH-2 study above include results from around 20 of the over 120 data tables the company plans to present. We expect to see additional data at the Future Leaders in Biotech conference early April 2013 and via a late breaker presentation at ECCMID mid-April 2013. Management hopes to be in position to present a full analysis from ESTABLISH-2 at ICAAC in September 2013. However, some interesting sub-set analysis was presented on the conference call on March 25, 2013. We present those data below:

EASTABLISH-2	Tedizolid 200mg 6 Days QD (n=332)	Linezolid 600mg 10 Days BID (n=334)	Comments
Efficacy By Infection Type			
Cellulitis / Erysipelas (n=166 / n=168)	**80.7%**	**80.4%**	**Difficult to treat population**
Major Cutaneous Abscess (n=68 / n=68)	**86.8%**	**89.7%**	
Wound Infection (n=98 / n=98)	**91.8%**	**81.6%**	**Mgmt looking into this**

…NDA Planned For 2H-2013…

Trius plans to file a new drug application (NDA) seeking U.S. approval for tedizolid in ABSSSI in September or October 2013. Trius recently noted they have completed enrolling all supporting studies necessary for the filing. The company is analyzing data from toxicology studies and hopes to have this completed by the third quarter 2013. We remind investors that the ESTABLISH-1 and ESTABLISH-2 trails were conducted under "evolving" endpoints with respect to ABSSSI. Both trials were conducted under special protocol assessments (SPA) with the U.S. FDA, and Trius mentioned on the conference call that SPA for the ESTBLAISH-2 study was amended to align with the finalized guidelines from the agency on ABSSI. Guidance is to file the marketing authorization application (MAA) seeking approval in the European Union during the first quarter of 2014.

Below we highlight some of the similarities and differences between the two programs.

Tedizolid Phase 3	ESTABLISH-1	ESTABLISH-2
Dosing	**Oral**	**IV-to-Oral**
Demographics	**US 80% / Ex-US 20%**	**US 47% / Ex-US 53%**
MRSA %	**42.6%**	**27.1%**
Primary Endpoint	**Lesion Spread & Absence of Fever**	**>20% Reduction In Lesion Spread**

Despite differences in dosing, demographics, percent of patients with MRSA, and the primary endpoint, the results between ESTABLISH-1 and ESTABLISH-2 are remarkably consistent.

Tedizolid Phase 3	Tedizolid		Linezolid	
	ESTABLISH-1	ESTABLISH-2	ESTABLISH-1	ESTABLISH-2
Efficacy Assessment				
>20% Decrease from Baseline in Lesion Area at 48-72 hours	78.0%	85.2%	76.1%	82.6%
Sustained Clinical Response at End of Therapy	87.0%	87.0%	87.8%	88.0%
Investigators Assessment of Clinical Response at 7-14 Days at End of Therapy	85.5%	88.0%	86.0%	87.7%
Cessation of Spread and Absence of Fever at 48-72 hours	79.5%	85.8%	79.4%	81.4%
Safety Assessment				
Treatment Emergent Adverse Events	40.8%	45.3%	43.3%	43.7%
Drug Related Averse Events	24.2%	20.5%	31.0%	24.8%
Gastrointestinal Adverse Events	16.3%	16.0%	25.4%	20.5%
Platelet Level Below Normal	9.2%	13.5%	14.9%	13.0%

EU Deal Is Next Major Catalyst

We expect that Trius would like to sign a commercialization deal for tedizolid in the European Union and keep U.S. rights for themselves. We remind investors that Bayer paid Trius $25 million upfront to license tedizolid for the Asia/Pacific region. That deal also included 25% of the future global development costs for the drug in ABBBI and pneumonia, $69 million in certain development, regulatory, and commercialization milestones, and double digit royalties (we model 15%) on sales.

The deal size for Europe is difficult to predict however. On one hand, the Bayer deal was signed in July 2011, before enrollment in ESTABLISH-1 had even completed. Now Trius has data from two positive phase 3 studies in ESTABLISH-1 and ESTABLISH-2. The U.S. NDA will be filed in the next six months. The EU MAA will be filed in early 2014. That dwarfs the resume that Trius had back in July 2011 when Bayer forked over $25 million. Before the Bayer deal, in May 2011, Trius stock traded with a market capitalization of around $150 million. Today, the market value is north of $325 million. The story has been significantly de-risked. The market is saying Trius is worth at least twice as much, so we assume potential partners will agree.

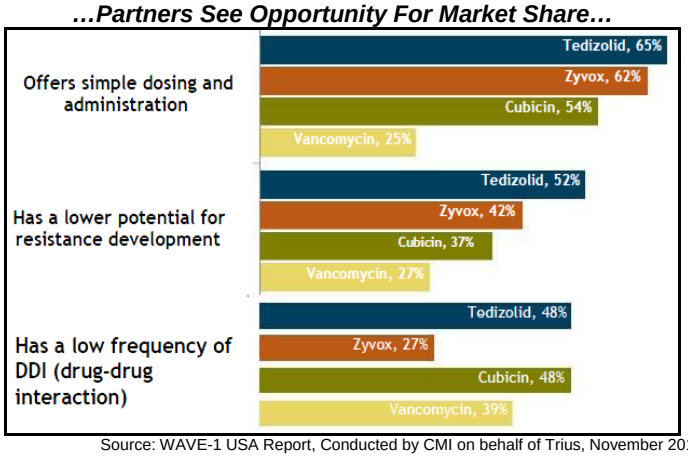
However, Europe is a stagnate market with difficult pricing. Growth in China and the rest of emerging Asia for drugs like Zyvox, Tygacil, and Cubicin is far ahead of the pace in Europe. In fact, sales of Zyvox (linezolid) were down year-over-year in 2012 to $302 million at Pfizer, versus $306 million in 2011. Sales of Tygacil were up only slightly in 2012 to $67 million versus $64 million in 2011. Emerging markets, however, showed strong growth for Zyvox, up to $224 million in 2012 versus $188 million in 2011. Any deal that Trius signs for tedizolid in Europe will take into consideration the market opportunity in Europe simply is not as large as Asia/Pacific.

We suspect that Trius would like to have a European deal in place before the MAA filing. However, with a solid cash position and plenty of work to be done between now and then in terms of presenting the data and preparing and filing the U.S. NDA, we do not expect Trius to wait around for a partner. Trius exited 2012 with $66.0 million in cash and investments. In January 2013, the company entered into an underwritten public offering by selling 7.169 million shares of common stock at $4.75 per share, resulting in net proceeds of $31.6 million. Taking into account an estimated operating burn of around $15 million in the first quarter 2013, we forecast that Trius will report roughly $80 to $85 million in cash as of March 31, 2013. We find this to be sufficient to fund operations throughout 2013.

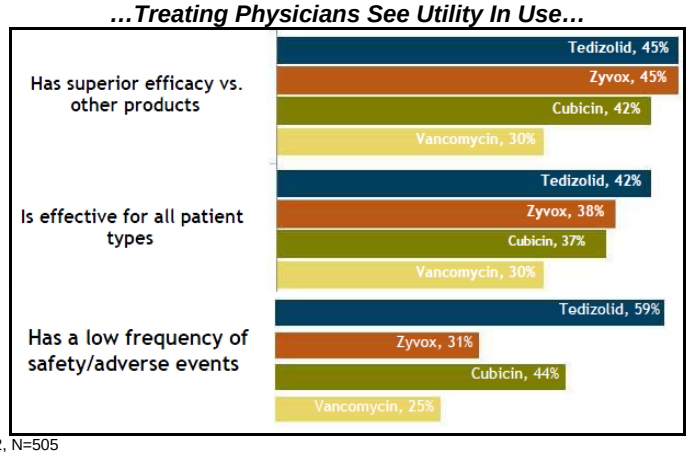
Trius plans to conduct a phase 3 pneumonia (lung) study with tedizolid to start before the end of the year. In the past, management has said they would also like to conduct a bacteremia (systemic infection) study with tedizolid. We suspect that may take place in 2014. Expanding the label indication for tedizolid is important to the future growth of the drug. With a full expanded label, tedizolid will have clear differentiation from its two closest competitors, Pfizer's Zyvox (linezolid), which is approve for us in skin and lung infections, and Cubists Cubicin (daptomycin), which is approved for skin and systematic infections. Trius goal with tedizolid is to gain approval in all three major indications of use.

We believe the company has amassed an attractive suite of clinical data that both potential commercial partners and doctors will see value in. Below is a highlight from some of the company's market research showing a strong potential for market share gains once approved:

…Partners See Opportunity For Market Share…



…Treating Physicians See Utility In Use…



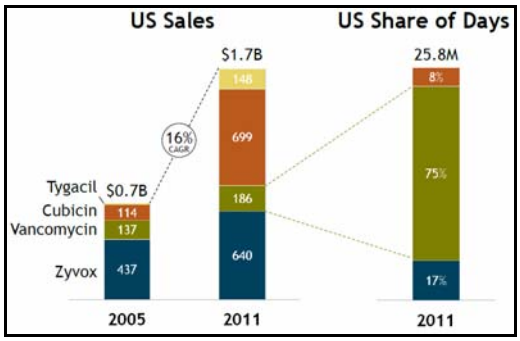
Source: WAVE-1 USA Report, Conducted by CMI on behalf of Trius, November 2012, N=505

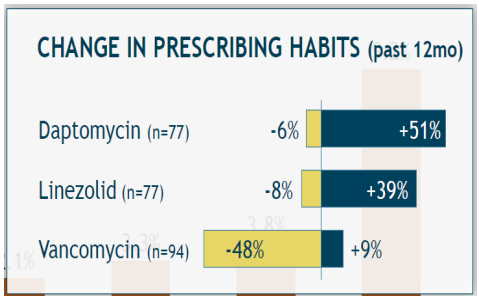
INVESTMENT THESIS

Commercial Potential Is Very Attractive

We see a significant commercial potential for tedizolid in the U.S. We believe peak sales in the $300 million to $400 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.

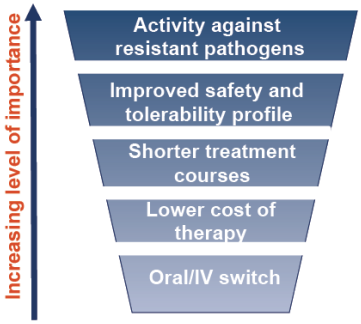
This is clearly a large market. U.S. sales for Zyvox, Cubicin, Tygacil, and generic vancomycin eclipsed $1.7 billion in 2012. Vancomycin prescriptions grew by 6% CAGR between 2005 and 2010. Yet, despite the presence of generic vancomycin, branded sales of Zyvox, Cubicin, and Tygacil grew by 20% CAGR. 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.



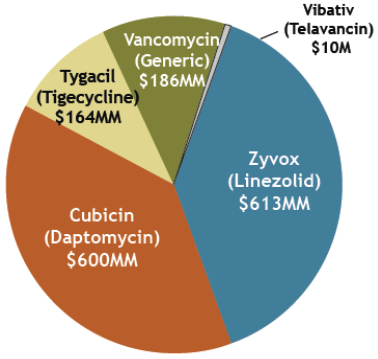


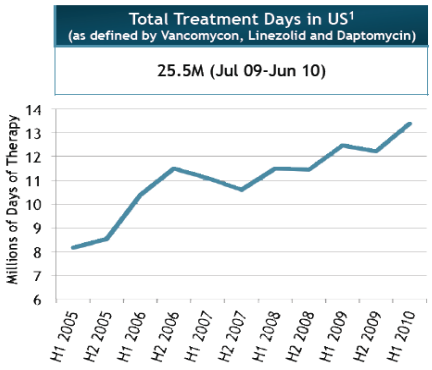
Initial market research conducted by management on formulary acceptance shows that with a non-inferior profile to Zyvox, tedizolid will see broad (~90%) Tier-2 coverage at parity pricing per course of treatment (~$1,500) to Zyvox. This includes a range of indications, including skin, HAP/VAP, Bacteremia,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

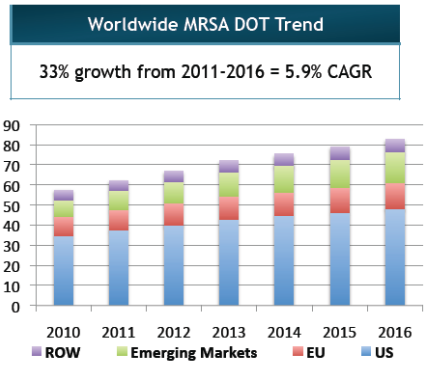
Trius held an R&D day in early December 2011 that offered perspective from two leading physicians with significant experience in treating patients with MRSA: Dr. Ralph Corey, Profession or Medicine and Infectious disease at Duke University and Dr. Jeff Kingsley, CEO of the Southeast Regional Research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







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

Stock Worth $12

We have built a 10-year discounted cash flow (DCF) model to value shares of Trius Therapeutics. Our market assumptions are as follows:

- U.S. launch of Tedizolid January 1, 2015 at parity pricing to Zyvox per course of treatment
- Gain of 5% market share (days) for U.S. hospital market, 10% U.S. out-patient market
- Partner for EU market with estimated $50 million upfront and 20% royalty on sales
- EU launch of Tedizolid in mid-2015 at EU partner.
- Peak U.S. sales $372 million in 2022
- Peak EU sales at $159 million in 2022
- Peak Asia/Pacific sales at $216 million in 2023
- Discount rate of 14.0%, with 3% terminal growth rate, $0 revenue contribution from Gyrase-B

Trius Therapeutics (TSRX)	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Tedizolid N.A. Sales (Full)	$0	$0	$15.4	$56.2	$121.3	$206.4	$291.9	$358.2	$383.9	$372.0	$368.3
YoY Growth	-	-	-	*264%*	*116%*	*70%*	*41%*	*23%*	*7%*	*-3%*	*-1%*
Royalty on Ex-N.A. Sales	$0	$0	$5.6	$16.2	$27.5	$37.2	$44.7	$52.4	$58.8	$63.4	$68.3
YoY Growth	-	-	-	*187%*	*70%*	*35%*	*20%*	*17%*	*12%*	*8%*	*8%*
Pipeline	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Grants, Licensing & Collabs	$30.0	$5.0	$35.0	$0.0	$15.0	$0.0	$15.0	$0.0	$0.0	$0.0	$0.0
Cash Revenues (in Millions)	$30.0	$5.0	$56.0	$72.3	$163.8	$243.7	$351.6	$410.6	$442.7	$435.4	$436.6
CoGS	*$0*	*$0*	*$1.5*	*$5.6*	*$11.5*	*$18.6*	*$24.8*	*$28.7*	*$30.7*	*$29.8*	*$29.5*
R&D	*$66.5*	*$50.0*	*$40.0*	*$35.0*	*$35.0*	*$35.0*	*$35.0*	*$35.0*	*$35.4*	*$34.8*	*$34.9*
SG&A	*$19.0*	*$30.0*	*$35.5*	*$39.6*	*$46.1*	*$54.6*	*$63.2*	*$69.8*	*$72.4*	*$71.2*	*$70.8*
Other Expenses	*$0*	*$13.0*	*$2.5*	*$7.8*	*$14.5*	*$21.7*	*$28.4*	*$34.0*	*$37.1*	*$37.9*	*$39.2*
EBITDA	($55.5)	($88.0)	($23.5)	($15.7)	$56.7	$113.7	$200.3	$243.1	$267.1	$261.7	$262.2
Depreciation and amortization	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$1.0*	*$1.5*	*$2.0*	*$2.5*	*$3.0*	*$3.5*
EBIT	**($56.0)**	**($88.5)**	**($24.0)**	**($16.2)**	**$56.2**	**$112.7**	**$198.8**	**$241.1**	**$264.6**	**$258.7**	**$258.7**
EBITDA margin	*-186.7%*	*-1770.0%*	*-42.9%*	*-22.4%*	*34.3%*	*46.3%*	*56.5%*	*58.7%*	*59.8%*	*59.4%*	*59.2%*
Cash Taxes	$0	$0	$0	$0	($2.8)	($22.5)	($63.6)	($77.2)	($84.7)	($82.8)	($82.8)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*5.0%*	*20.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*
Discounted Cash Flow											
Cash Income	($56.0)	($88.5)	($24.0)	($16.2)	$53.4	$90.2	$135.2	$164.0	$179.9	$175.9	$175.9
Net Cash Changes	$5.5	$6.0	$6.5	$7.0	$7.5	$8.0	$8.5	$9.0	$9.5	$10.0	$10.5
Post-Tax Operating Cash Flow	**($50.5)**	**($82.5)**	**($17.5)**	**($9.2)**	**$60.9**	**$98.2**	**$143.7**	**$173.0**	**$189.4**	**$185.9**	**$186.4**
Dividends / Payments	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**($50.5)**	**($82.5)**	**($17.5)**	**($9.2)**	**$60.9**	**$98.2**	**$143.7**	**$173.0**	**$189.4**	**$185.9**	**$186.4**

Assumptions	
Discount Rate:	14.0%
Terminal Growth:	3%
Net Cash Position:	$82.5

Valuation	
10-Year Model:	$177.7
Terminal Value:	$383.5
Firm Value:	**$643.7**

Price Target	
Basic Outstanding:	47.9
Warrants / Options:	5.6
Price Price:	**$12.05**

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

PROJECTED FINANCIALS

Trius Therapeutics, Inc.
Income Statement

Trius Tx	2011 A	2012 E	Q1 E	Q2 E	Q3 E	Q4 E	2013 E	2014 E	2015 E
Tedizolid (N.A. Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$15.4
YOY Growth	-	-	-	-	-	-	-	-	-
Tedizolid (EU Royalties)	$0	$0	$0	$0	$0	$0	$0	$0	$2.6
YOY Growth	-	-	-	-	-	-	-	-	-
Tedizolid (Asia/EM Royalties)	$0	$0	$0	$0	$0	$0	$0	$0	$2.6
YOY Growth	-	-	-	-	-	-	-	-	-
Total Tedizolid Revs	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$21**
YOY Growth	-	-	-	-	-	-	-	-	-
Contracts & Collaborations	**$41.0**	**$27.2**	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$20.0**	**$20.0**	**$20.0**
YOY Growth	*100.0%*	*-33.7%*	-	-	-	-	*-26.4%*	*0.0%*	*0.0%*
Total Revenues	**$41.0**	**$27.2**	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$20.0**	**$20.0**	**$40.6**
YOY Growth	*100.0%*	*-33.7%*	-	-	-	-	*-26.4%*	*0.0%*	*103.0%*
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$1.5
Product Gross Margin	*0.0%*	*0%*	-	-	-	-	*0.0%*	*0%*	*0%*
R&D	$49.5	$69.0	$17.5	$16.5	$16.0	$16.5	$66.5	$50.0	$40.0
% R&D	-	*253.9%*	-	-	-	-	*332.5%*	*250.0%*	*98.5%*
SG&A	$11.3	$15.4	$4.5	$4.7	$4.8	$5.0	$19.0	$30.0	$35.5
% SG&A	*27.6%*	*56.6%*	-	-	-	-	*95.0%*	*100.0%*	*87.5%*
Operating Income	($19.8)	($57.2)	($17.0)	($16.2)	($15.8)	($16.5)	($65.5)	($60.0)	($36.5)
Operating Margin	*-48.4%*	*-210.5%*	-	-	-	-	*-327.5%*	*-250.0%*	*-89.9%*
Interest & Other Income	$1.6	$3.3	$1.5	$1.0	$0.5	$0.5	$3.5	$2.5	$2.5
Pre-Tax Income	($18.3)	($53.9)	($15.5)	($15.2)	($15.3)	($16.0)	($62.0)	($57.5)	($34.0)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($18.3)	($53.9)	($15.5)	($15.2)	($15.3)	($16.0)	($62.0)	($57.5)	($34.0)
Net Margin	*-44.5%*	*-198.4%*	-	-	-	-	*-310.0%*	*-237.5%*	*-83.7%*
Reported EPS	**($0.69)**	**($1.42)**	**($0.34)**	**($0.32)**	**($0.32)**	**($0.33)**	**($1.28)**	**($1.15)**	**($0.65)**
YOY Growth	*-70.9%*	*105.5%*	-	-	-	-	*-9.7%*	*-25.7%*	*-31.9%*
Basic Shares Outstanding	26.5	38.1	45.0	47.9	48.0	48.5	48.5	50.0	52.5

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

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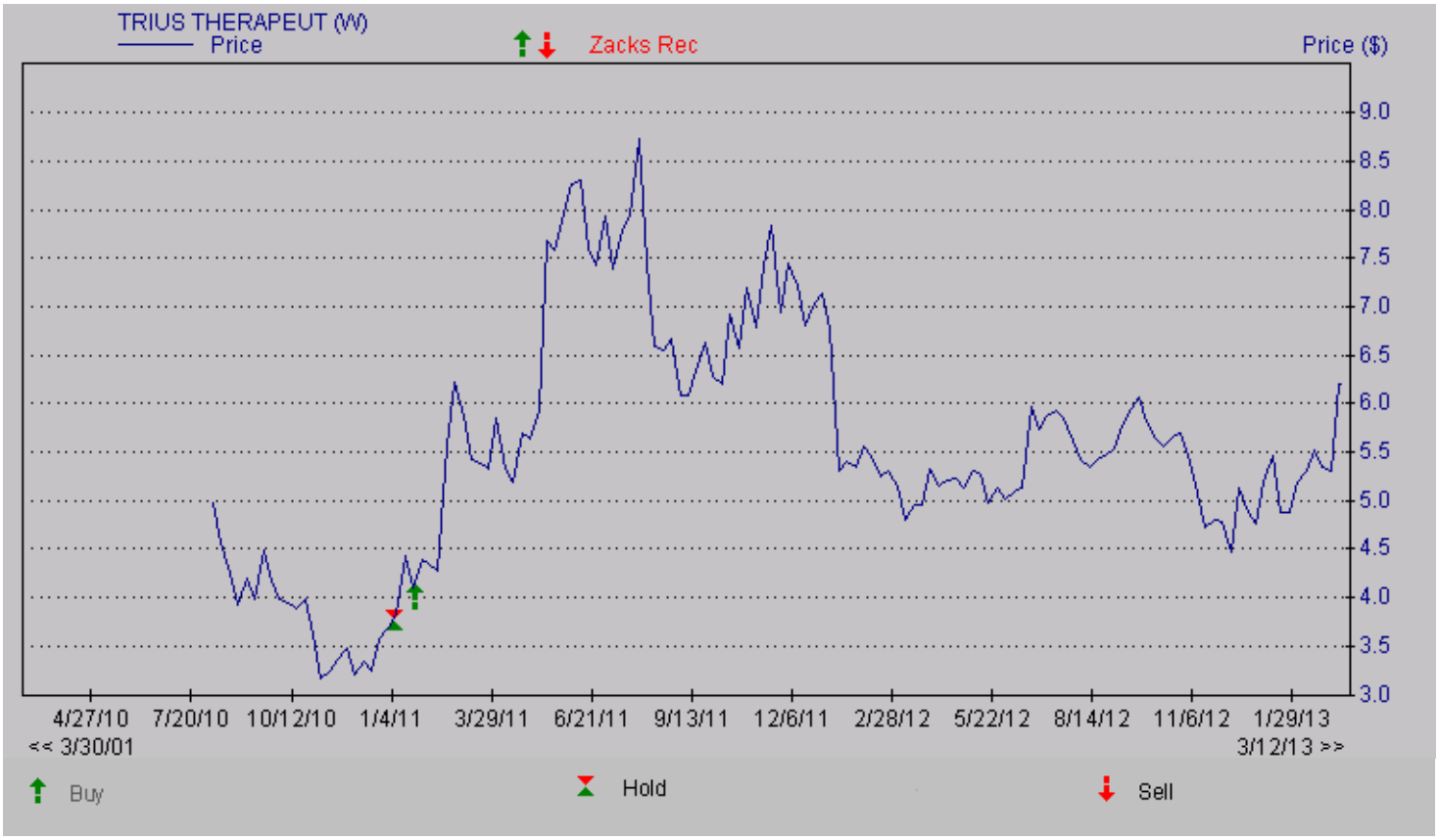

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