Zacks Small-Cap Research

August 12, 2011
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Trius Therapeutics (TSRX-NASDAQ)

TSRX: Torezolid Poised To Be Best In Class For MRSA…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	01/24/2011
Current Price (08/12/11)	$6.99
Target Price	**$12.00**

UPDATE

Earlier this month Trius announced a development and commercialization alliance with Bayer Pharma AG for the rights to Torezolid in Asia/Pacific and emerging markets. Bayer paid Trius $25 million upfront, with the potential for an additional $69 million in backend milestones and double-digit royalties on sales.

We are maintaining our 'Outperform' rating and $12 price target on Trius Therapeutics. We believe the company's phase 3 candidate, Torezolid, is poised to be "best-in-class" for acute bacterial skin and skin structure infections (ABSSSI) and methicillin-resistant *Staphylococcus aureus* (MRSA).

SUMMARY DATA

52-Week High	**$8.74**
52-Week Low	**$3.02**
One-Year Return (%)	**49.23**
Beta	**-0.04**
Average Daily Volume (sh)	**64,479**
Shares Outstanding (mil)	**29**
Market Capitalization ($mil)	**$194**
Short Interest Ratio (days)	**3.94**
Institutional Ownership (%)	**10**
Insider Ownership (%)	**61**
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	1.5 A	2.1 A	1.9 A	2.5 A	8.0 A
2011	2.7 A	2.9 A	5.2 E	5.2 E	16.0 E
2012					25.0 E
2013					25.0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$5.08 A	-$2.69 A	-$0.57 A	-$0.37 A	-$2.36 A
2011	-$0.43 A	-$0.40 A	-$0.28 E	-$0.28 E	-$1.35 E
2012					-$0.82 E
2013					-$0.50 E

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

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WHAT'S NEW

Second Quarter Financials

On August 11, 2011, Trius reported financial results for the second quarter 2011. Total revenues in the quarter were $2.9 million, and consisted of the company's federal research contract with the Defense Threat Reduction Agency (DTRA). Net loss for the quarter totaled $10.0 million, or $0.40 per share. This was in-line with expectations. Trius exited the second quarter ended June 30, 2011 with $56.7 million in cash and investments. We note this amount does not include the recent $25 million upfront payment from Bayer AG for licensing the Asia/Pacific and emerging market rights to torezolid, which we discuss below. We forecast that Trius will exit the third quarter 2011 with roughly $75 million in cash and investments, enough to fund operations through the phase 3 program.

Bayer Takes Asia/Pacific Rights

On July 27, 2011, Trius announced it had formed a strategic collaboration to develop and commercialize torezolid in Asia/Pacific and emerging markets (Africa, Middle East, and Latin America) with Bayer Pharma AG. Trius has retained full development and commercialization rights outside the Bayer territory, which includes unencumbered rights in the U.S., Canada, and Europe. Under terms of the agreement, Bayer paid Trius a $25 million upfront payment and will support approximately 25% of the future development costs of torezolid required for global approval in acute bacterial skin and skin structure infections (ABSSSI) and pneumonia. In addition, Trius is eligible to receive up to $69 million in certain development, regulatory, and commercial milestones, along with double digit royalties (we model 15%) on sales. On the conference call, CEO Jeff Stein noted that 50% of these milestones are pre-commercialization. We are particularly excited about the deal for a number of reasons:

- ✓ Firstly, Bayer is an outstanding commercial partner, with expertise in anti-infectants including Cipro and Avalox. Bayer has the financial strength and experience to launch torezolid in Asia, including China, and potential emerging markets across the Africa and the Middle East. Bayer just recently moved its commercial operations for Asia to China. We expect Bayer to commence clinical work in China / Japan shortly.

- ✓ Secondly, the $25 million upfront payment provides Trius with much needed cash to continue the ongoing phase 3, TR-701-p3-A, program. As of May 2011, this trial was about 65% complete. Bayer will also reimburse Trius for approximately 25% of global development costs, including 100% in China and Japan. This includes unfinished preclinical and CMC work. Also, Trius can earn up to $69 million in potential backend milestone, which include additional indications into skin and lung infections. Respiratory infections like Avian Flu and SARS are significant medical concern in Asia, and we believe torezolid has significant potential to treat lung infections, a key differentiator from Cubists Cubicin, in China and Japan.

- ✓ Thirdly, Trius retains the unencumbered rights to develop, commercialize or separately partner in the U.S., Canada, and the EU. We believe the above deal with Bayer is just a taste of what could come in terms of a U.S. or European deal for torezolid following successful completion of the first phase 3 trial.

- ✓ Finally, it validates our belief that torezolid is a potential blockbuster drug, with differentiating factors from both Pifzer's Zyvox (linezolid) and Cubist's Cubicin (daptomycin), and reinforces our assumption that Trius can sign a significantly larger deal for torezolid in unlicensed territories in 2012.

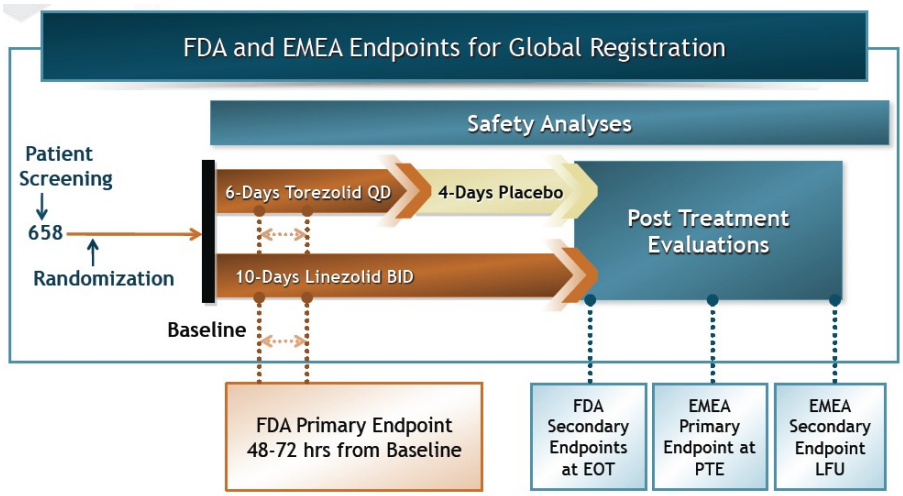
SPA Secured for 2nd Phase 3 Trial

On August 5, 2011, Trius announced that it has reached an agreement with the U.S. FDA for a Special Protocol Assessment (SPA) on the design of its second planned phase 3 study for the intravenous and oral dose forms of Torezolid for the treatment of ABSSSI. This trial will compare the efficacy and safety of 200mg QD torezolid for six 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. The primary endpoint will be the cessation of infected lesion spread and absence of fever at 48 to 72 hours following initiation of treatment. Secondary endpoints will include sustained clinical response at the end of therapy visit, and the investigator's assessment of clinical response at all visits and clinical success at the post treatment evaluation visit. The goal is to show non-inferiority of torezolid vs. linezolid. If this is met, an assessment of superiority of torezolid with respect to the primary efficacy endpoint will also be made. This would be a "home run" outcome. We expect Trius to start this second pivotal study in the fourth quarter 2011.

INVESTMENT THESIS

Phase 3 Torezolid Update

Study-112 ➔ Enrollment in the company's first phase 3 trial with torezolid is progressing on plan. Enrollment has recently been expanded to include 60+ sites in Europe and Latin America. This nearly triples the number of sites, as previously the trial was only enrolling at around 30 sites in North America earlier this year. With things now accelerated, we believe enrollment should complete in the next few months. Management guidance is for data in early 2012. We remind investors that this program is testing torezolid vs. Pfizer's Zyvox (linezolid) in 650+ patients under a U.S. FDA special protocol assessment (SPA). The trial tests 200mg once-daily (QD) Torezolid for 6 days head-to-head in a non-inferiority study to 600mg twice-daily (BID) Zyvox (linezolid) for 10 days.

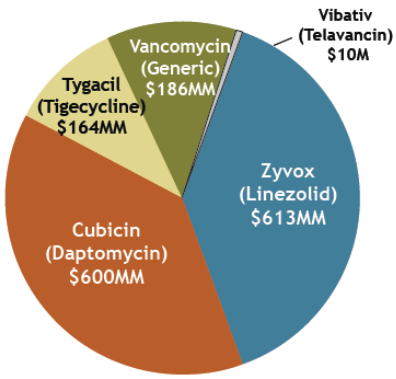


Study-113 ➔ Recently, Trius announced that it has reached an agreement with the U.S. FDA for a SPA on the design of its second planned phase 3 study (Study-113) for the IV-to-Oral step-down trial. This trial will compare the efficacy and safety of 200mg QD torezolid for six days to 600mg BID linezolid (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 expect Trius to start this second pivotal study in the fourth quarter 2011.

The primary endpoint for both trials will be the cessation of infected lesion spread and absence of fever at 48 to 72 hours following initiation of treatment. Secondary endpoints will include sustained clinical response at the end of therapy visit, and the investigator's assessment of clinical response at all visits and clinical success at the post treatment evaluation visit. The goal is to show non-inferiority of torezolid vs. linezolid. If this is met, an assessment of superiority of torezolid with respect to the primary efficacy endpoint will also be made. This would be a "home run" outcome. With respect to the IV-to-Oral step-down trial (Study-113), we will be looking to see if patients transition to oral medication on torezolid earlier in the treatment phase than linezolid. We note that having both an IV and oral dosage formulation is a key differentiator to Cubist's Cubicin (daptomycin). Between Zyvox and Cubicin, we estimate these drugs have over 80% of the dollar market share in MSSA/MSRA.

U.S. Sales 2010 - $1.56 Billion

- ✓ 20% CAGR in branded sales from 2005 – 2010
- ✓ 6% CAGR in vancomycin sales from 2005 – 2010
- ✓ Vancomycin success rate at declining for MRSA



…Torezolid Poised To Be Best-In-Class…

Despite the rapid growth in new antibiotics such as Cubicin and Tygacil, we believe there is significant room for improvement in the treatment paradigm. Torezolid is a second generation oxazolidinone being developed for the treatment of serious gram-positive infections, including MRSA. Based on clinical data from phase 1 and phase 2 studies, Torezolid offers several key advantages over the market leading product in Pfizer's Zyvox (linezolid), a first-generation oxazolidinone with worldwide sales over $1.1 billion in 2010. These advantages include far more rapid bacteriocidal onset, far more convenient once-daily dosing, a shorter course of therapy at only 6 days vs. the 10 to 14 days recommended wit h Zyvox, and superior cure rates in difficult-to-treat MRSA infections.

Trius plans to make Torezolid available in both an oral and IV formulation, providing an advantage to Pfizer's Tygacil and Cubist's Cubicin. These three products generated sales of $1.4 billion in the U.S. in 2010, gaining sizable market share as the therapeutic window on generic vancomycin is rapidly closes. We believe physicians will quickly convert the next leap forward in the treatment of acute bacterial skin and skin structure infections (ABSSSI) and methicillin-resistant *Staphylococcus aureus* (MRSA) in Torezolid.

Trius and Bayer are currently in discussions with the U.S. FDA on a third phase 3 program to focus on lung infections. This could be another significant differentiator to Cubist's Cubicin (daptomycin). We expect management to secure an SPA for this third phase 3 trial in the fourth quarter 2011, and start the study shortly thereafter. We expect that management will also seek to conduct a study in bacteremia in 2012, providing yet another strong point of differentiation to Pfizer's Zyvox (linezolid).

…Key Advantages vs. Both Zyvox & Cubicin…

	Zyvox (linezolid)	Cubicin (daptomycin)	Torezolid
IV & Oral Formulation	YES	NO	YES
Rapid Efficacy Onset	NO	YES	YES
Once Daily Dosing	NO	YES	YES
Short Course of Therapy	NO	NO	YES
Skin Infections	YES	YES	YES
Active In Lung Infections	YES	NO	YES
Bacteremia	NO	YES	YES

The chart below is a retrospective analysis of cross trial response rates for ABSSSI and cSSSI based on the primary endpoint for phase 3 trials for Zyvox and the phase 2 data from Trius' torezolid.

Measurement	Linezolid*	Torezolid#
ABSSSI Primary Endpoint Cessation of spread, afebrile, ≥ 1 systemic sign, lesion size ≥ 75cm^2 at 48-72 hrs from baseline	78.8%	91.3%
cSSSI Primary Endpoint Clinical response at test-of-cure	91.2%	98.2%

Source: Trius Inc., Pfizer, Inc.

Based on current timelines, we are expecting a new drug application (NDA) in 2013, with FDA approval in 2014. We expect that Trius will look to commercialize Torezolid in the U.S. on its own and partner for the opportunity outside the U.S. We see worldwide sales of $800 million in 2020.

VALUATION & RECOMMENDATION

Trius Undervalued By Any Measure

We see Torezolid as having significant market potential based on a clear superior profile to the two market-leading products in Pfizer's Zyvox (linezolid) and Cubist's Cubicin (daptomycin). Torezolid offers rapid efficacy onset, convenient once-daily dosing, a short course of therapy, and powerful efficacy. Pfizer's Zyvox posted worldwide sales of $1.176 billion in 2010 despite its limitations. We believe that Trius' phase 3 program will prove that 6 once-daily 200mg Torezolid pills are superior to 10 twice-daily (20 total) 600mg Zyvox pills.

…On Future Cash Flow…

Once approved, we believe Torezolid will be a share gainer. There is clear precedence that backs-up our belief. The market began shifting from generic vancomycin to the more effective Zyvox a decade ago, and newer products such as Cubicin and Tygacil are gaining share on Zyvox now. Assuming FDA and EMEA approvals in 2014, we are modeling Torezolid worldwide sales of $800 million by 2020. This assumes a cost of around $1500 per Rx, or $250 per day for an average use of 6 days. We assume Trius seeks to commercialize Torezolid on its own in the U.S., and partner outside the U.S. (Bayer deal already done for Asia / EM). Based on our discounted cash flow (DCF) analysis, we see Trius fairly valued at market cap of roughly $350 million based on these projections.

…By Comparative Deal Analysis…

Future cash flow is traditionally the best way to value a company. But what if Trius never even makes it to 2015 as an independent company? Anti-infectants have been an area where we have seen significant deal activity over the past decade. Accordingly, we see an excellent way to value Trius by looking at previous deals between larger pharmaceutical organizations and small companies with late-stage antibiotics for serious gram-positive infections.

Comparative Deals For Late-Stage Antibiotics	**Total Deal Value[1]**
In April 2005, Johnson & Johnson acquired Peninsula Pharmaceuticals. Peninsula Pharma was in phase 3 studies with doripenem, a broad-spectrum antibiotic under U.S. FDA Fast Track designation for VAP.	$245 Million
In July 2005, Pfizer acquired Vicuron Pharmaceuticals. Vicuron was in phase 3 development for dalbavancin, a broad-spectrum antibiotic for cSSSI, and under U.S. FDA review with anidulafungin (Eraxis), a powerful anti-fungal agent.	$1.9 Billion
In November 2005, Astellas entered into a licensing agreement with Theravance. Theravance was just entering phase 3 development with telavancin for cSSSI. Telavancin, a bactericidal lipoglycopeptide, is now sold as branded Vibativ.	$231 Million
In December 2006, Forest Labs acquired Cerexa Inc. Cerexa was just entering phase 3 trials for ceftaroline, a cephalosporin for MRSA and other serious gram-positive cSSSI.	$580 Million
In October 2008, Novartis entered into a licensing agreement with Paratek. Paratek was in phase 3 development with PTK-0796 for cSSSI and MRSA. PTK-0796 is a broad-spectrum aminomethylcycline oral & IV antibiotic.	$485 Million
In January 2009, The Medicines Company acquired Targanta Therapeutics. Targanta was in phase 3 for oritavancin, a broad-spectrum antibiotic for cSSSI and HA-MRSA.	$138 Million
In December 2009, Forest Labs expanded its licensing agreement with Novexel. The agreement expanded Forest's interest in a NLX-104 / ceftazidime combination product for the treatment of cSSSI and MRSA. NLX-104 is a beta-lactamase inhibitor.	$305 Million
In December 2009, Cubist Pharmaceuticals acquired Calixa Therapeutics. Calixa was in phase 2 trials with CXA-201, a cephalosporin / tazobactam combination,	$403 Million
In February 2011, Astellas entered into a licensing agreement with Optimer Pharma. Optimer was in phase 3 trials with fidaxomicin for the treatment of *C. difficile* infection (CDI) in Europe, the Middle East, and Africa.	$224 Million

1 – Includes potential backend milestones

The chart above clearly shows the interest of big pharma in this area. Pfizer, J&J, Astellas, Novartis, and Forest Labs are all major players, along with specialty pharma names such as Cubist. If we ascribe 65% of the value of Pfizer's acquisition of Vicuron to anidulafungin, which was under FDA review at the time, we still arrive at a deal value for dalbavancin north of $650 million. That puts the average deal value, all-in, at nearly $400 million for a late-stage antibiotic for cSSSI / ABSSSI or MRSA. We can back-out the $25 million Trius has already received from Bayer for the Asia / Pacific and emerging market rights, along with $69 million potential backend milestones, and we arrive at a potential "deal" value for Trius of around $325 million.

…Vs. The Competition…

Direct Competitors	**Market Capitalization**
Cubist Pharmaceuticals: 1 FDA approved product in Cubicin (daptomycin) with $625 Million in sales worldwide, and 2 phase 2 products in CXA-201 (gram-negative bactericide) and CB-315 (gram-positive bactericide). ⇨ 2010 Revs: $636 million. 2010 Net Income (non-GAAP): $173 million, Cash: $909 million	$1.95 Billion
Optimer Pharmaceuticals: 2 products under FDA review in fidaxomicin for *C. difficile* infection and prulifloxacin for infectious diarrhea. Also working on new indications and an oral formulation for fidaxomicin. ⇨ 2010 Revs: $1.5 million. 2010 Est. Net Income: -$47 million, Cash: $49.4 million	$360 Million

Cubist and Optimer are the most directly comparable companies to Trius. We see Cubist as the model company for Trius to follow. In our view, Torezolid has similar market potential 5 years after launch to where Cubicin is right now, posting U.S. sales in 2010 of $600 million. By the time Torezolid is under FDA review in 2014, we expect the preclinical programs currently funded by NIAID and DTRA to be in mid-to-late stage trials. Cubist's market capitalization of roughly 11-times that of Trius seems to overly discount this future potential. The market is valuing Optimer at over 4-times the value of Trius, despite that we see Torezolid as having significantly greater sales potential to fidaxomicin and prulifloxacin.

We see Trius following closely in the footsteps of both Cubist and Optimer. In our view, we see a market capitalization of $250 million more fairly valuing the company in relation to its two closest peers.

Rating Outperform / Target of $12

In January 2011 we initiated coverage of Trius Inc. with an Outperform rating. We are confident in the outcome of the company's ongoing phase 3 trial testing Torezolid vs. Pfizer's Zyvox (linezolid) for the treatment of acute bacterial skin and skin structure infections (ABSSSI). We see significant market share gains for Torezolid over the three market leading products, Zyvox, Cubicin, and Tygacil. The current market cap of only ~$230 million undervalues the story in our view.

Based on a combination of three valuation methods, DCF, comparative deal analysis, and comparison to peer group, we see the company fairly valued at a market capitalization of roughly $325 million.

Valuation Method	**Projected Market Cap.**
Discounted Cash Flow	~ $350 Million
Take-Out Value / Comparative Deals	~ $325 Million
Peer-Group Analysis	~ $250 Million
Estimated Fair Value	~$340 Million

This equates to a target price of $12 per share based on 28.5 million shares outstanding. We note that there are roughly 1.7 million warrants outstanding that become exercisable at $8.40 per share in November 2011.

PROJECTED FINANCIALS

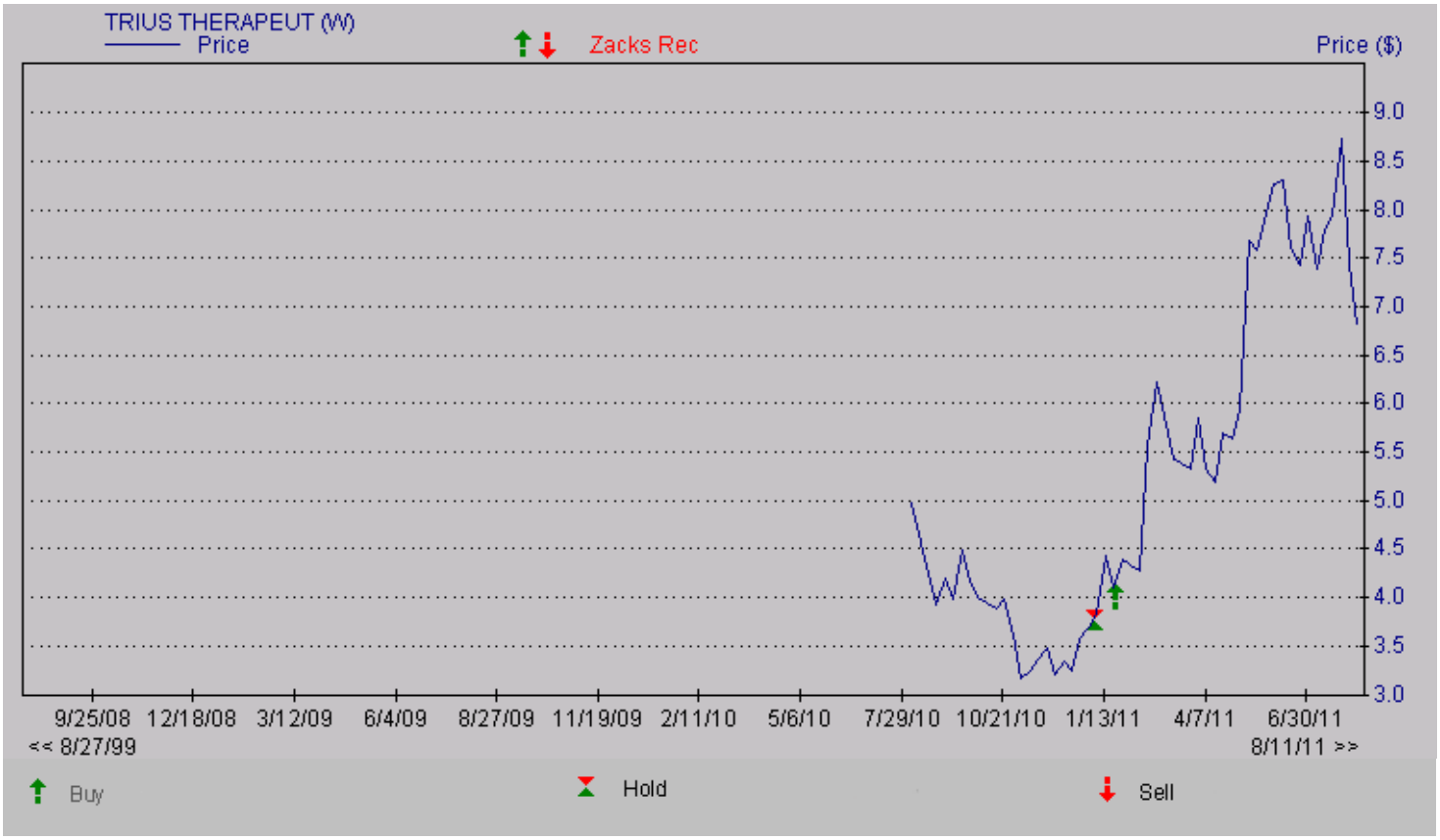
Trius Therapeutics, Inc.
Income Statement

	2009 A	2010 A	Q1 A	Q2 A	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Torezolid (N.A. Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-
Torezolid (EU Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-
Torezolid (Asia/EM Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Torezolid Revs	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Contracts & Collaborations	**$5.0**	**$8.0**	**$2.7**	**$2.9**	**$5.2**	**$5.2**	**$16.0**	**$25.0**	**$25.0**	**$20.0**
YOY Growth	-	-	-	-	-	-	*100.0%*	*56.5%*	*0.0%*	*-20.0%*
Total Revenues	**$5.0**	**$8.0**	**$2.7**	**$2.9**	**$5.2**	**$5.2**	**$16.0**	**$25.0**	**$25.0**	**$20.0**
YOY Growth	-	*60.1%*	-	-	-	-	*100.0%*	*56.5%*	*0.0%*	*-20.0%*
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*0%*	*0.0%*	-	-	-	-	*0.0%*	*0%*	*0%*	*0%*
R&D	$23.0	$23.3	$10.4	$10.4	$10.6	$11.0	$42.4	$40.0	$30.0	$30.0
% R&D	-	-	-	-	-	-	-	*160.0%*	*120.0%*	*150.0%*
SG&A	$4.1	$5.4	$2.3	$2.5	$2.4	$2.5	$9.7	$10.0	$10.5	$11.0
% SG&A	-	-	-	-	-	-	*60.8%*	*40.0%*	*42.0%*	*55.0%*
Operating Income	($22.2)	($20.7)	($10.1)	($10.0)	($7.8)	($8.3)	($36.2)	($25.0)	($15.5)	($21.0)
Operating Margin	*0%*	*0.0%*	-	-	-	-	*-226.4%*	*-100.0%*	*-62.0%*	*-105.0%*
Interest & Other Income	($0.5)	($3.2)	$0.0	$0.0	($0.1)	($0.1)	($0.2)	($0.5)	($0.4)	($0.2)
Pre-Tax Income	($22.7)	($23.9)	($10.1)	($10.0)	($7.9)	($8.4)	($36.4)	($25.5)	($15.9)	($21.2)
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	($22.7)	($23.9)	($10.1)	($10.0)	($7.9)	($8.4)	($36.4)	($25.5)	($15.9)	($21.2)
Net Margin	*0%*	*0.0%*	-	-	-	-	*-227.7%*	*-102.0%*	*-63.6%*	*-106.0%*
Reported EPS	**($31.09)**	**($2.36)**	**($0.43)**	**($0.40)**	**($0.28)**	**($0.28)**	**($1.35)**	**($0.82)**	**($0.50)**	**($0.64)**
YOY Growth	-	*-92.4%*	-	-	-	-	*-42.9%*	*-39.1%*	*-39.6%*	*29.3%*
Basic Shares Outstanding	0.7	10.1	23.6	25.3	28.6	30.2	26.9	31.0	32.0	33.0

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

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