Zacks Small-Cap Research

March 13, 2013
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Trius Therapeutics (TSRX-NASDAQ)

TSRX: ESTABLISH-2 Data Imminent…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	01/24/2011
Current Price (03/13/13)	$6.21
Target Price	**$12.00**

UPDATE

Data from Trius second phase 3 study, ESTABLISH-2, with tedizolid is expected the last week of March 2013. Data from the first study, ESTABISH-1, was positive and we believe dramatically lowers the risk profile of holding the stock into the data. 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 ~$300 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	**$6.34**
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					-$0.95 E
2015					-$0.60 E

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WHAT'S NEW

Financial Results

On March 12, 2013, Trius Therapeutics reported financial results for the fourth quarter and full year 2012. Total revenues in the quarter were $5.2 million, and consisted of $1.0 million in contract research from the company's NIAID and DTRA grants and $4.1 million collaborative and licensing fees from Bayer Pharma AG, the company's partner in Asia/Pacific market for tedizolid phosphate. For the full year 2012, Trius recognized a total of $8.5 million in contract research revenues and $18.7 million in revenues from Bayer, which included a $5.0 million milestone payment in the first quarter for the successful completion of the first phase 3 study, ESTABLISH-1 (TR701-112).

Net loss in the fourth quarter totaled $14.2 million, or 36 cents per share. Research and Development expenses in the quarter totaled $16.5 million. S&GA expense totaled $4.7 million. R&D was lower than expected, down from the $19.3 million in the third quarter 2012. We remind investors that enrollment in the second phase 3 study, ESTABLISH-2, completed on December 10, 2012. SG&A was higher than expected, up from $4.4 million in the third quarter and $3.0 million earlier in the year. Management noted pre-commercialization activities and higher personnel costs associated with increasing headcount leading to the uptick in operating expenses during the quarter. For the full year 2012, Trius reported a net loss of $53.9 million, or $1.42 per share. Loss was driven by $69.0 million in R&D and $15.4 million in SG&A. We expect the trend of slightly lower R&D and ramping SG&A to continue in 2013 as the company continues to prepare for the commercialization of tedizolid.

…Solid Cash Position…

Trius exited 2012 with $66.0 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. In October 2012, Trius sold 612,133 shares of common stock under the CSPA to raise net proceeds of $3.4 million. 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.

ESTABLISH-2 Results Imminent

As noted above, Trius completed enrollment in the second phase 3 study, ESTABLISH-2, on December 10, 2012. We remind investors that ESTABLISH-1 completed enrollment on September 15, 2011 and reported top-line data 95 days later on December 19, 2011. Assuming a similar timeline, 95 days after December 10, 2012 would be March 15, 2013. We suspect that compiling data from ESTABLISH-2 (118 clinical sites globally) will take an extra week compared to ESTABLISH-1 (84 clinical sites globally). We note ESTABLISH-2 had far more sites outside the U.S., thus we are expecting data the last week of March 2013. We remain optimistic on the results of ESTABLISH-2, believing that tedizolid will demonstrate non-inferiority to linezolid on the primary endpoint of response rate, defined as cessation of spread and absence of fever at 48-72 hours.

…Next Up – File the NDA, Sign an EU Deal, Initiate a Phase 3 Pneumonia Study…

Assuming the results from ESTABLISH-2 are positive, we expect that Trius will be in position to file the new drug application (NDA) on tedizolid for acute bacterial skin and skin structure infections (ABSSSI) during the second half of 2013. Management recently noted they have completed all supporting studies necessary for the filing.

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, the company's Asia/Pacific partner paid Trius $25 million upfront to license tedizolid for Asia/Pacific. They deal also includes 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. If ESTABLISH-2 is successful, Trius will be able to go to marketing partners with two positive phase 3 trials with tedizolid and potentially a U.S. NDA under review. 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 $300 million. The story has been significantly de-risked. The market is saying Trius is worth 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.

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 key 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.

Fundamentals Remain Strong

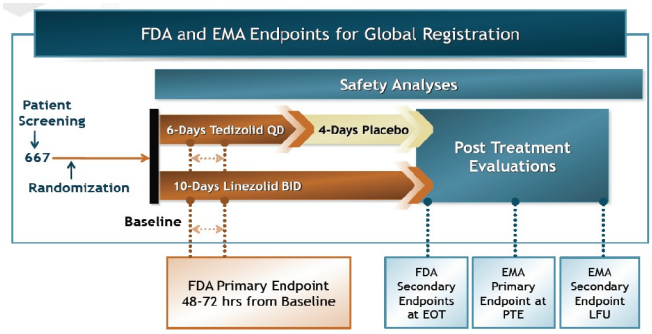
We believe fundamentals at Trius remain solid. We see the development of tedizolid, with data from its second phase 3 trial expected in the next two weeks, as low risk. Management has presented impressive safety and efficacy data from the first phase 3 trial at recent medical meetings, including the IDWeek2012 meeting in October 2012 and ICAAC in September 2012.

Finally, Trius is well funded. We model over $80 million in cash will be on hand at the end of the first quarter 2013. We see fair-value at $12 per share based on our 10-year DCF model. We think tedizolid is a $400 million drug in the U.S. and $750 million globally. We believe Trius is an attractive take-over candidate for a specialty pharmaceutical company looking to enhance its anti-infectant pipeline. Once tedizolid is commercialized, we think investors will start to pay more attention and assign value to the company's preclinical pipeline, which includes Gyrase-B, currently in IND-enabling studies.

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.

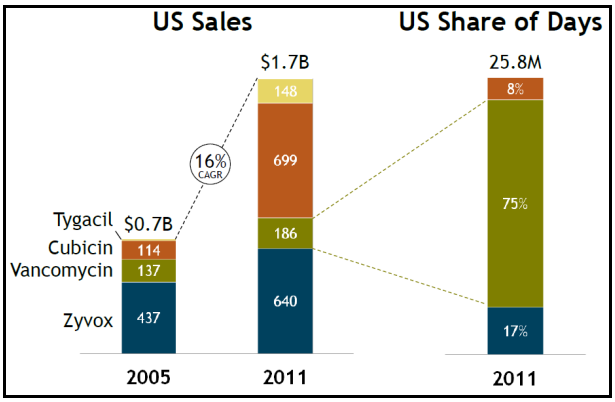
Besides better tolerability, we noted the significant administrative and convenience advantages of tedizolid versus linezolid, including a shorter course of treatment (6 days vs. 10 days), once-daily dosing, and bioequivalence between the oral and IV dose.

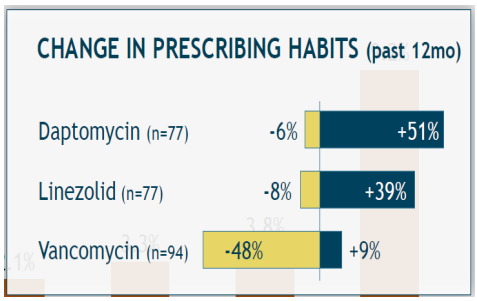
We think tedizolid can gain market share from linezolid based on these advantages. With the above marketing advantages on safety and convenience and a superior efficacy claim, we think tedizolid could have best-in-class. Based on the top-line data from -112, we still think tedizolid will be a very nice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

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.

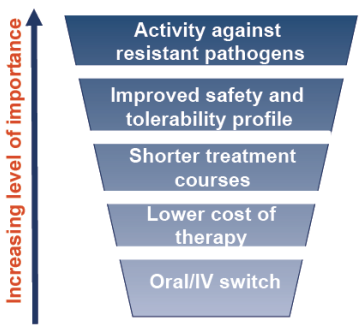
This is clearly a large market. U.S. sales for Zyvox, Cubicin, Tygacil, and generic vancomycin eclipsed $1.7 billion in 2011. Vancomycin prescriptions grew by 6% CAGR between 2005 and 2010. Yet, despite the presence of generic vancomycin, branded sales of Zyvox, Cubicin, and Tygacil grew by 20% CAGR. 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.



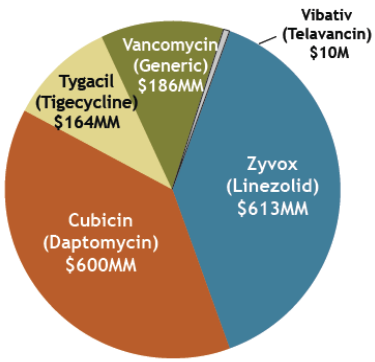


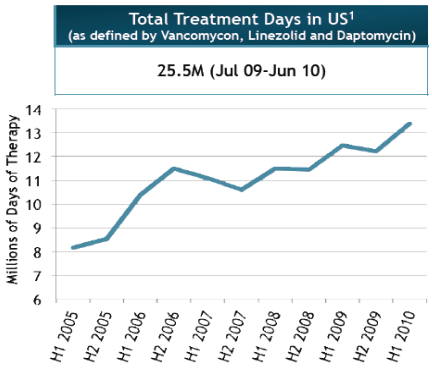
Initial market research conducted by management on formulary acceptance shows that with a non-inferior profile to Zyvox, tedizolid will see broad (~90%) Tier-2 coverage at parity pricing per course of treatment (~$1,500) to Zyvox. This includes a range of indications, including skin, HAP/VAP, Bacteremia,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

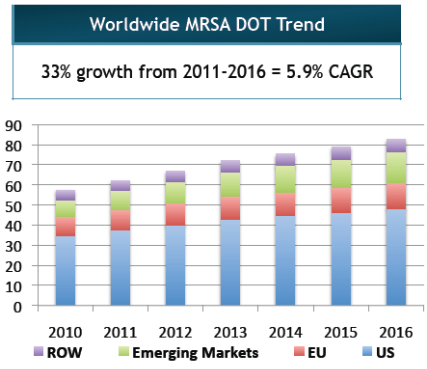
Trius held an R&D day in early December 2011 that offered perspective from two leading physicians with significant experience in treating patients with MRSA: Dr. Ralph Corey, Profession or Medicine and Infectious disease at Duke University and Dr. Jeff Kingsley, CEO of the Southeast Regional Research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

Trius Tx	2011 A	Q1 A	Q2 A	Q3 A	Q4 E	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	$0	$0	$0	$0	$15.4
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Tedizolid (EU Royalties)	$0	$0	$0	$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	$0	$0	$0	$2.6
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Total Tedizolid Revs	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$21**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-
Contracts & Collaborations	**$41.0**	**$9.8**	**$6.2**	**$6.0**	**$5.2**	**$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**	**$9.8**	**$6.2**	**$6.0**	**$5.2**	**$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	$0	$0	$0	$0	$1.5
Product Gross Margin	*0.0%*	-	-	-	-	*0%*	-	-	-	-	*0.0%*	*0%*	*0%*
R&D	$49.5	$16.8	$16.4	$19.3	$16.5	$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	$3.0	$3.3	$4.4	$4.7	$15.4	$4.5	$4.7	$4.8	$5.0	$19.0	$20.0	$33.0
% SG&A	*27.6%*	-	-	-	-	*56.6%*	-	-	-	-	*95.0%*	*100.0%*	*81.4%*
Operating Income	($19.8)	($10.0)	($13.5)	($17.8)	($16.0)	($57.2)	($17.0)	($16.2)	($15.8)	($16.5)	($65.5)	($50.0)	($34.0)
Operating Margin	*-48.4%*	-	-	-	-	*-210.5%*	-	-	-	-	*-327.5%*	*-250.0%*	*-83.7%*
Interest & Other Income	$1.6	$2.4	($0.9)	$0.1	$1.7	$3.3	$1.5	$1.0	$0.5	$0.5	$3.5	$2.5	$2.5
Pre-Tax Income	($18.3)	($7.6)	($14.4)	($17.7)	($14.2)	($53.9)	($15.5)	($15.2)	($15.3)	($16.0)	($62.0)	($47.5)	($31.5)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($18.3)	($7.6)	($14.4)	($17.7)	($14.2)	($53.9)	($15.5)	($15.2)	($15.3)	($16.0)	($62.0)	($47.5)	($31.5)
Net Margin	*-44.5%*	-	-	-	-	*-198.4%*	-	-	-	-	*-310.0%*	*-237.5%*	*-77.6%*
Reported EPS	**($0.69)**	**($0.22)**	**($0.37)**	**($0.46)**	**($0.36)**	**($1.42)**	**($0.34)**	**($0.32)**	**($0.32)**	**($0.33)**	**($1.28)**	**($0.95)**	**($0.60)**
YOY Growth	*-70.9%*	-	-	-	-	*105.5%*	-	-	-	-	*-9.7%*	*-25.7%*	*-36.9%*
Basic Shares Outstanding	26.5	35.2	38.7	38.8	39.6	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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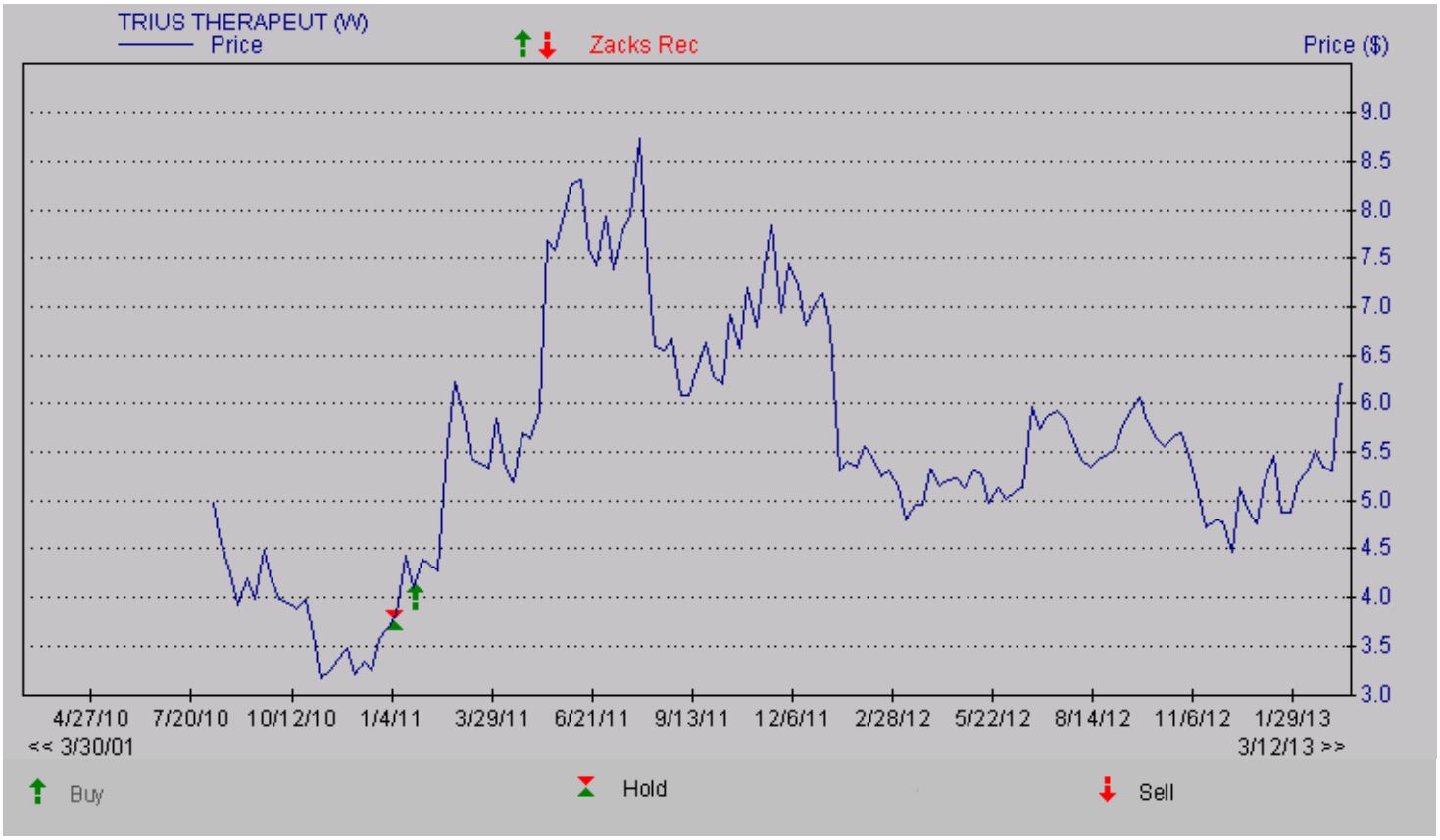

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