Zacks Small-Cap Research

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Transcept Pharmaceuticals, Inc. (TSPT-NASDAQ)

TSPT: FDA Meeting Set For September…

UPDATE

Transcept expect to meet with the U.S. FDA in September 2011 to discuss the complete response letter (CRL) received in July 2011 on Intermezzo. Management expects to make a decision on the future of the program following receipt of the minutes from this meeting, which we would expect to take place in October or November.

The FDA may have put Intermezzo to sleep. Question is, can management wake it back up? On their side is sound scientific rational, a fairly sizable market opportunity, long and defensible IP, and $60 million in cash.

Our rating is Neutral, with a $5 target.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	07/12/2011
Current Price (08/12/11)	$3.02
Target Price	**$5.00**

SUMMARY DATA

52-Week High	**$11.73**
52-Week Low	**$2.75**
One-Year Return (%)	**-60.51**
Beta	**2.29**
Average Daily Volume (sh)	**210,862**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$39**
Short Interest Ratio (days)	**0.97**
Institutional Ownership (%)	**29**
Insider Ownership (%)	**43**
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 2010 Estimate	**N/A**
P/E using 2011 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Average,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	3.1 A	3.1 A	3.1 A	3.1 A	12.5 A
2011	3.1 A	3.1 A	1.1 E	0 E	7.4 E
2012					0 E
2013					0 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.14 A	-$0.15 A	-$0.21 A	-$0.20 A	-$0.69 A
2011	-$0.14 A	-$0.17 A	-$0.38 E	-$0.38 E	-$1.07 E
2012					-$1.03 E
2013					-$0.81 E

Zacks Projected EPS Growth Rate - Next 5 Years % **N/A**

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WHAT'S NEW

Second Quarter Financials

On August 11, 2011, Transcept reported financial results for the second quarter 2011. Total revenues in the quarter were $3.1 million and comprised of amortization of the $25 million upfront payment from Purdue for Intermezzo in August 2009. As a reminder, Transcept is recognizing this payment over a 24-month period that will fully amortize this August 2011. As a result, we expect revenues of only $1.1 million in the third quarter 2011 and then no future revenues for remainder of the year.

Net loss for the second quarter totaled $2.2 million, or $0.17 per share. This was in-line with our expectations. Transcept exited the second quarter ended June 30, 2011 with $56.7 million in cash and investments ($4.41 per share). Burn for the second quarter was $3.7 million. As a reminder, in July 2011 Transcept announced plans to reduce operating expenses by eliminating approximately 45% of its workforce. Transcept expects to record a restructuring charge of approximately $1.1 million in the third quarter of 2011 as a result of severance and benefit continuation expenses. The organizational change will reduce current annualized payroll and benefit expenses by approximately $2.1 million. We expect burn in the third quarter to be around $3.0 million.

FDA Meeting Set For September 2011

Transcept expect to meet with the U.S. FDA in September 2011 to discuss the complete response letter (CRL) received in July 2011 on Intermezzo. Management expects to make a decision on the future of the program following receipt of the minutes from this meeting, which we would expect to take place in October or November.

In the CRL, the FDA noted that during its review of the Intermezzo NDA resubmission it became concerned that those patients with higher zolpidem blood levels from Intermezzo could be at risk of unacceptable next-day impairment, specifically with respect to driving ability. The FDA further hypothesized that such patients may belong to distinct and identifiable demographic groups.

A path forward for Transcept may be to, first off, identify these patients and qualify the risk factors associated with potential next-day impairment. Patients with low body weight or body mass index (BMI) and the elderly are two more susceptible groups that management may look to develop risk mitigation strategies to prevent potentially dangerous zolpidem blood levels in the event of driving too soon after dosing. Potential paths forward include lowering the Intermezzo dose from 3.5mg to 1.75mg, requiring patients to spend more time in bed, to employing patient selection strategies that essentially "black box" the drug for this demographic group.

Ultimately, we believe that Transcept will need do conduct some sort of pharmacokinetic profiling study for these patients. This will most likely be followed by another driving study. Our concern is that a mitigation strategy, or REMS, that is too restrictive would greatly reduce the sales potential for the drug. Case in point, the marketing message for Somaxon's Silenor as a non-scheduled device hasn't really paid off (Silenor sales in the second quarter 2011 were only $6.2 million). Intermezzo, with a potentially restrictive REMS, would have no chance in our view. This all remains to be seen following the meeting with the FDA.

Our Rating is 'Neutral'

We currently rate the shares 'Neutral' with a price target of $5 per share. We have completely removed Intermezzo from our model. We currently do not account for any revenues from Intermezzo or TO-2061 in our model going forward. Our price target is residual cash value.

PROJECTED FINANCIALS

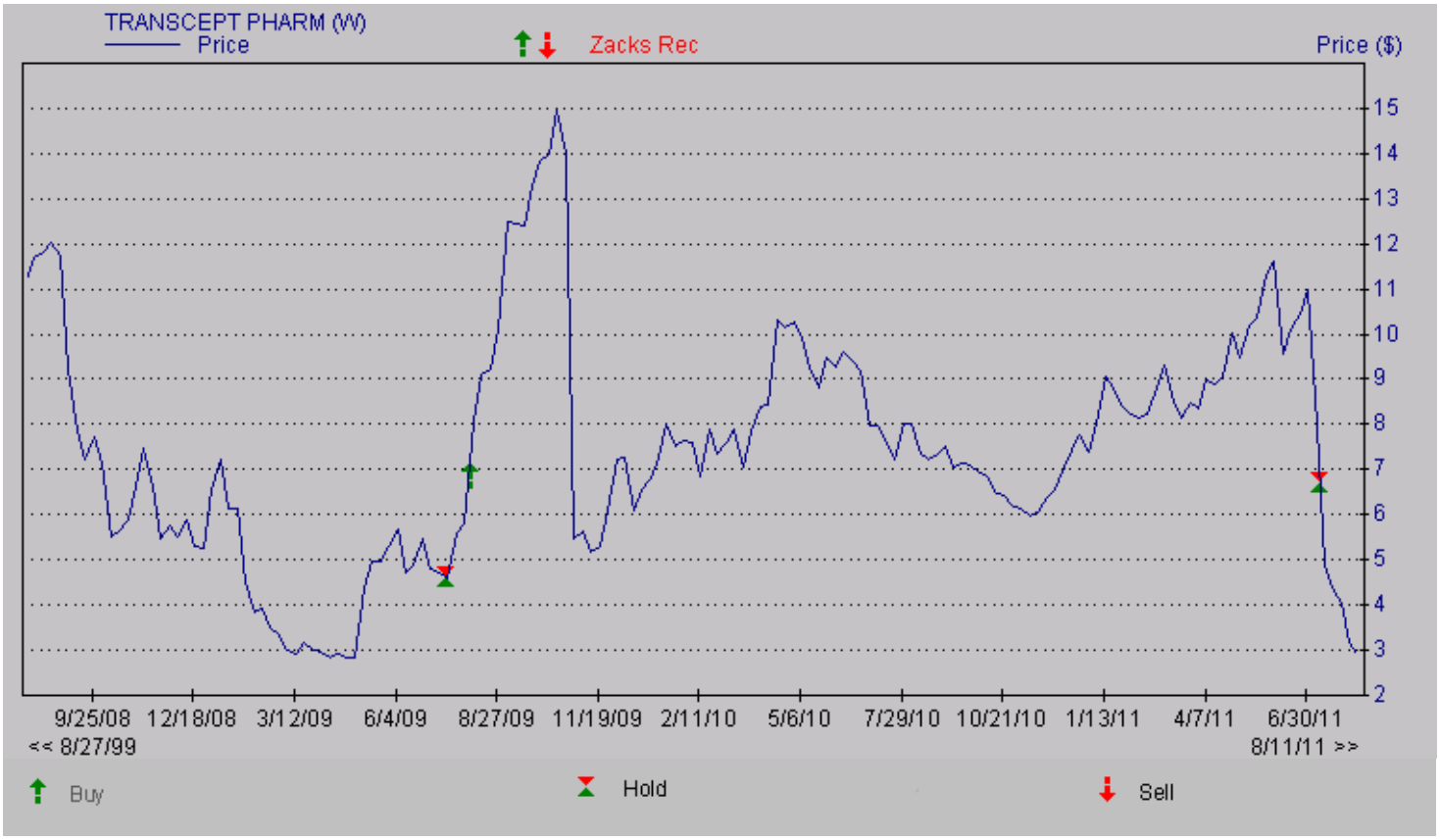
Transcept Pharmaceuticals, Inc.
Income Statement

	2009 A	2010 A	Q1 A	Q2 A	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Intermezzo (US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Intermezzo (Ex-US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Intermezzo Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Collaborations / Milestones	**$5.2**	**$12.5**	**$3.1**	**$3.1**	**$1.1**	**$0**	**$7.4**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Setrodon	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Total Revenues	**$5.2**	**$12.5**	**$3.1**	**$3.1**	**$1.1**	**$0**	**$7.4**	**$0**	**$0**	**$0**
YOY Growth	-	*140.0%*	-	-	-	-	*-41.2%*	*-100.0%*	*-100.0%*	*#DIV/0!*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-	-	-
SG&A	$16.0	$11.0	$2.5	$2.6	$3.6	$2.3	$11.0	$8.5	$9.0	$9.5
% SG&A	*308.0%*	*88.3%*	*81.4%*	*82.6%*	*327.3%*	-	*150.0%*	-	-	-
R&D	$9.0	$10.7	$2.5	$2.8	$2.6	$2.8	$10.7	$10.0	$10.0	$10.0
% R&D	*172.9%*	*85.5%*	*79.7%*	*88.4%*	*236.4%*	-	*145.0%*	-	-	-
Merger & Other Costs	$2.2	$0	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($22.1)	($9.2)	($1.9)	($2.2)	($5.1)	($5.1)	($14.3)	($18.5)	($19.0)	($19.5)
Operating Margin	-	-	-	-	-	-	*-195.0%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Interest & Other Net	$0.3	($0.1)	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	$0.4	$0.5	$0.5
Pre-Tax Income	($21.8)	($9.3)	($1.9)	($2.2)	($5.1)	($5.1)	($14.4)	($18.1)	($18.5)	($19.0)
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	($2.7)	($5.6)	($5.7)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*15.0%*	*30.0%*	*30.0%*
Net Income	($21.8)	($9.3)	($1.9)	($2.2)	($5.1)	($5.1)	($14.4)	($15.4)	($13.0)	($13.3)
YOY Growth	-	-	-	-	-	-	-	*6.6%*	*-10.3%*	*-13.6%*
Net Margin	-	-	-	-	-	-	*-196.4%*	*#DIV/0!*	*#DIV/0!*	*#DIV/0!*
Reported EPS	**($1.79)**	**($0.69)**	**($0.14)**	**($0.17)**	**($0.38)**	**($0.38)**	**($1.07)**	**($1.03)**	**($0.81)**	**($0.78)**
YOY Growth	-	-	-	-	-	-	-	*-4.0%*	*-24.3%*	*-23.7%*
Shares Outstanding	12.2	13.4	13.5	13.5	13.5	13.6	13.5	15.0	16.0	17.0

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

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