Zacks Equity Research

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Transcept Pharmaceuticals, Inc. (TSPT-NASDAQ)

TSPT: Don't Lose Sleep Over Transcept, There's Deep Value At This Level.

UPDATE

We are maintaining our positive bias on Transcept Pharmaceuticals. We believe the stock is significantly undervalued at this level and the market is overly pessimistic on the ability of management to address the issues raised in the FDA's complete response letter from last October 2009. From what we have seen, management has an excellent plan to answer the questions brought up by the agency and we think everything could be ready to re-file by October 2010. That puts an action date in April 2011. With nearly $90 million in cash still on the books at year-end 2009 and a market value of only $105 million, Transcept offers enormous upside once Intermezzo is finally approved by the FDA.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	08/10/2009
Current Price (03/24/10)	$7.77
Target Price	**$10.00**

SUMMARY DATA

52-Week High	**$15.12**
52-Week Low	**$2.80**
One-Year Return (%)	**149.84**
Beta	**2.39**
Average Daily Volume (sh)	**9,557**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$105**
Short Interest Ratio (days)	**4.56**
Institutional Ownership (%)	**0**
Insider Ownership (%)	**40**
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 Rank in Industry	**84 of 136**

ZACKS ESTIMATES

Revenue
(millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	0 A	0 A	2.1 A	3.1 A	5.2 A
2010	3.1 E	3.1 E	3.1 E	3.1 E	12.5 E
2011					36.0 E
2012					48.2 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2009	-$0.95 A	-$0.54 A	-$0.29 A	-$0.18 A	-$1.79 A
2010	-$0.15 E	-$0.17 E	-$0.19 E	-$0.18 E	-$0.69 E
2011					$0.34 E
2012					$0.68 E

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

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WHAT'S NEW

Transcept Submits Revised Protocol To The FDA…

On January 20, 2010, Transcept management met with the U.S. FDA to discuss the complete response letter issued October 28, 2009 on Intermezzo. The letter brought up issues on potential inadvertent re-dosing in a single night and inadvertent dosing with less than four hours of bedtime remaining. The FDA also requested additional data demonstrating that Intermezzo, when taken as directed in the middle of the night (MOTN), would not present an unacceptable risk of next day driving ability. Prior to attending the meeting, management submitted a revised proposal for the resubmission of the Intermezzo new drug application (NDA) to the FDA for evaluation and comment. In this briefing document, Transcept proposed a new Intermezzo bedside unit-dose package and patient instructions designed to reduce the possibility of patient dosing errors.

The proposed revised packaging for Intermezzo looked similar to how Merck has packaged Maxalt-MLT (rizatriptan benzoate). Maxalt is an orally disintegrating tablet, similar to the sublingual design of Intermezzo, indicated for the treatment of migraine attacks in adults. The packaging for Maxalt includes a large individually-wrapped ("unit of use") tablet inside a pouch roughly the size of a cocktail napkin. Anywhere from 8 to 12 of these packets can fit inside a standard box. The pouch is child resistant, requiring a fold-and-tear method to open and expose the pill. The pouch is also large enough to provide substantial instructions for use (IFU) and cautionary language on each individually-wrapped unit. And finally, the pouch is air-tight to protect the sublingual formulation from degradation.

…FDA Issues Mixed Response…

On February 19, 2010, Transcept received the minutes from the FDA meeting. In the minutes, the FDA indicated that the revised packaging:

- Appeared to reduce the potential for inadvertently taking more than one dose in a single night.

- However, the FDA expressed a remaining concern that the revised packaging may not adequately address the risk of dosing with less than four hours of time remaining in bed, with particular regard to the possibility of impaired driving.

Transcept and the FDA also reviewed the types of data that could support the evaluation of the proposed packaging and instructions, including data from pre-approval assessments of patient understanding of dosing instructions and a potential patient use study of the new Intermezzo packaging. As requested by the FDA, Transcept has provided information on the challenges and limitations of pre-approval patient use studies, and has submitted a plan to assess and optimize patient understanding of the new packaging and patient instructions.

…Driving Study To Begin in Shortly…

To further understand the safety of dosing Intermezzo in the middle of the night, Transcept has proposed to the FDA to conduct a pre-approval highway driving study to assess the effect of Intermezzo on driving ability beginning at approximately three hours and four hours post-dosing. The proposal was submitted to the FDA on February 16, 2010. Transcept is still waiting to hear back from the FDA on an ok for the design for this study. However, based on what we've seen in the past from driving studies, Transcept will probably seek to enroll 30 to 35 patients (in The Netherlands) testing 3 arms: Intermezzo, placebo, and an active control (zopiclone) in a cross-over design. These studies are typically very quick with only a few months to analyze the data. Total cost should be around $1 million. Our best guess is that management will be in position to re-file for approval around October 2010. Assuming a standard (class-II) review of six-months, we could be looking at FDA action in Intermezzo around April 2011.

Approval in April 2011 will be 10 months after the June 30, 2010 full milestone payment deadline from Purdue. As a reminder, the milestone then declines by $2 million each month starting in July 2010, so by April 2011 Transcept loses out 10 months, or $20 million. Still, including the transfer of the manufacturing and intellectual property to Purdue, approval will earn Transcept $10 million, so the total milestone upon approval will still be a respectable $20 million. This is on top of the $25 million upfront Transcept received in August 2009, and an additional $80 million in sales related milestones and royalties on the drug that can be earned in the future.

…IP Strengthened…

On March 23, 2010, Transcept announced that the second patent covering the composition and use of Intermezzo (zolpidem tartrate sublingual tablet) has been issued by the U.S. Patent and Trademark Office. Transcept has previously announced the issuance of a Notice of Allowance for claims under the application for this patent, U.S. Patent Application Serial No. 11/833,323, on November 4, 2009. The newly issued patent, U.S. Patent No. 7,682,628, titled "Compositions for Delivering Hypnotic Agents Across the Oral Mucosa and Methods of Use Thereof," will expire no earlier than February 2025.

INVESTMENT THESIS

Intermezzo Looks To Fill A Much Needed Void…

Insomnia remains a significant problem in the U.S. and Europe, and as such, there exists an attractive market opportunity for the launch of a new pharmaceutical product with differentiating characteristics. We estimate that nearly 70 million American adults (30% prevalence rate) are affected by some form of insomnia or sleep disorder. This can be characterized as difficulty falling asleep, waking frequently during the night and not being able to return to sleep, or waking up not feeling refreshed. A significant number of patients suffer from waking up frequently during the night and not being able to return to sleep. For many of these patients, there is no observed difficulty in falling asleep. Thus, existing medications that offer only sleep onset claims do little to solve the problem. Research shows that 35% of the general population reports awakening at least 3 nights per week.

Research also shows a significant void in the insomnia market remains for that 35% of the adult population that suffer from nocturnal awakenings. The ideal pharmaceutical product to address this unmet medical need would be an oral pro re nata (as needed) dosing of a rapidly effective molecule that can be taken with little to no next-day residual effects as soon as 3 to 4 hours later.

…Purdue Pharma On Board, Unlikely To Walk-Way…

In August 2009, Transcept signed a licensing and commercialization agreement for Intermezzo in the U.S. with privately-held Purdue Pharma. The deal included a $25 million upfront payment from Purdue to Transcept, along with the potential for an additional $30 million in approval and $90 million in sales and IP related milestones. We note that Transcept received a patent allowance for Intermezzo in early November 2009. This will trigger an additional $10 million milestone payment from Purdue upon approval. Purdue will pay double-digit royalties to Transcept ranging up to the mid-twenty percent level on U.S. net sales of Intermezzo. Transcept has the right to co-promote the drug to the psychiatry market as soon as the 1-year anniversary of the commercial launch by Purdue. Purdue will pay Transcept an additional double-digit royalty on sales of Intermezzo to psychiatrists.

From a sales standpoint, we think peak U.S. sales are around $500 million. We arrive at this figure as follows:

- 225 million adult Americans…35% with nocturnal awakenings…80% without onset issues…
- 11% currently seek Rx…10% eventually turn into Intermezzo users…
- Intermezzo costs $5 per pill, with average 3 pills per week…
- 225 million * 35% * 80% * 11% * 10% * 150 pills/year * $5 per pill = $520 million

By 2014, we think Intermezzo can capture about 1/2 of this peak sales opportunity. We think the European market is probably about 1/2 to 3/4 of the size of the U.S. market. Upside to this $500 million peak U.S. sales figure could come from increasing any of these components. Heavy marketing and promotion by Purdue in the primary care market should help expand the 11% that currently seek Rx help for nocturnal awakenings upwards to 15%, or greater closure on turning these Rx seekers into actual users of Intermezzo.

We note that despite the delay in approval, Purdue should remain committed to Intermezzo. The company has no ongoing costs associated with the product until approval, so there is essentially no reason for them to walk-way from the deal. The $25 million upfront milestone has already been paid. Purdue is not going to sink $25 million into Transcept just to walk way after what looks to be about an 18 month delay. Until approval, Purdue just waits. Plus, the approval milestone of $30 million is reduced by $2 million per month after June 30, 2010, so Purdue has baked protection into the terms of the agreement.

Stock Significantly Undervalued…

We are confident in the risk and safety profile of Intermezzo dosed 4 hours prior to awaking in the morning. Transcept has made available additional supportive analyses of data from a previously conducted Intermezzo pharmacokinetic and pharmacodynamic study at time points up to four hours post-dosing. The article, published in a 2008 article titled "Daytime pharmacodynamic and pharmacokinetic evaluation of low-dose sublingual transmucosal zolpidem hemitartrate" in the journal Human Psychopharmacology, concludes that an as-needed ("pro re nata") dosing of a sublingual transmucosal zolpidem lozenge may be the ideal pharmaceutical candidate for patients that suffer from middle of the night awakenings. We are confident that the planned driving study will clearly demonstrate that correct (on label) dosing of Intermezzo will not result in meaningful risk with respect to next day functionality or driving ability.

We are maintaining our positive rating on Transcept despite the delay. The stock is now trading with a market capitalization of only $104 million, just $15 million above the cash on the balance sheet of $89 million at year end 2009. This far undervalues the company in our view. Earlier this month we witnessed the approval of Somaxon Pharmaceutical's (SOMX) Silenor for the treatment of sleep maintenance insomnia. As a result, Somaxon's stock soared from a market value of $20 million to now $220 million. In our view, the market is applying a similar steep discount to Transcept, with an enterprise value of only $15 million less the cash balance. Once Intermezzo is approved in about a year, we would expect a similar rapid revaluation to significantly higher levels.

PROJECTED FINANCIALS

Transcept Pharmaceuticals, Inc.
Income Statement

	2008 A	2009 A	Q1 E	Q2 E	Q3 E	Q4 E	2010 E	2011 E	2012 E	2013 E
Intermezzo (US Sales)	$0	$0	$0	$0	$0	$0	$0	$37.0	$97.0	$158.0
Intermezzo (Ex-US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$45.0	$110.0
Intermezzo Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$8.7**	**$28.2**	**$50.3**
YOY Growth	-	-	-	-	-	-	-	-	*224.3%*	*78.5%*
Collaborations / Milestones	**$0**	**$5.2**	**$3.1**	**$3.1**	**$3.1**	**$3.1**	**$12.5**	**$27.3**	**$20.0**	**$20.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$5.2**	**$3.1**	**$3.1**	**$3.1**	**$3.1**	**$12.5**	**$36.0**	**$48.2**	**$70.3**
YOY Growth	-	-	-	-	-	-	*140.0%*	*187.9%*	*33.9%*	*45.9%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	-	-	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
SG&A	$7.9	$16.0	$3.0	$3.1	$3.2	$3.3	$12.6	$21.5	$25.0	$27.0
% SG&A	-	*308.0%*	*96.0%*	*99.2%*	*102.4%*	*105.6%*	*100.8%*	*59.7%*	*51.9%*	*38.4%*
R&D	$10.4	$9.0	$2.2	$2.4	$2.6	$2.4	$9.6	$10.0	$12.5	$15.0
% R&D	-	*172.9%*	*70.4%*	*76.8%*	*83.2%*	*76.8%*	*76.8%*	*27.8%*	*25.9%*	*21.3%*
Merger & Other Costs	$2.0	$2.2	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($20.3)	($22.1)	($2.1)	($2.4)	($2.7)	($2.6)	($9.7)	$4.5	$10.7	$28.3
Operating Margin	-	-	-	-	-	-	-	*12.5%*	*22.2%*	*40.3%*
Interest & Other Net	$0.3	$0.3	$0.1	$0.1	$0.1	$0.1	$0.4	$0.5	$0.6	$0.5
Pre-Tax Income	($20.0)	($21.8)	($2.0)	($2.3)	($2.6)	($2.5)	($9.3)	$5.0	$11.3	$28.8
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$1.1	$7.2
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*10.0%*	*25.0%*
Net Income	($20.0)	($21.8)	($2.0)	($2.3)	($2.6)	($2.5)	($9.3)	$5.0	$10.2	$21.6
YOY Growth	-	-	-	-	-	-	-	-	*103.9%*	*112.7%*
Net Margin	-	-	-	-	-	-	-	*13.9%*	*21.1%*	*30.7%*
Reported EPS	**($7.03)**	**($1.79)**	**($0.15)**	**($0.17)**	**($0.19)**	**($0.18)**	**($0.69)**	**$0.34**	**$0.68**	**$1.40**
YOY Growth	-	-	-	-	-	-	-	-	*97.1%*	*105.8%*
Shares Outstanding	2.8	12.2	13.4	13.5	13.5	13.6	13.5	14.5	15.0	15.5

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

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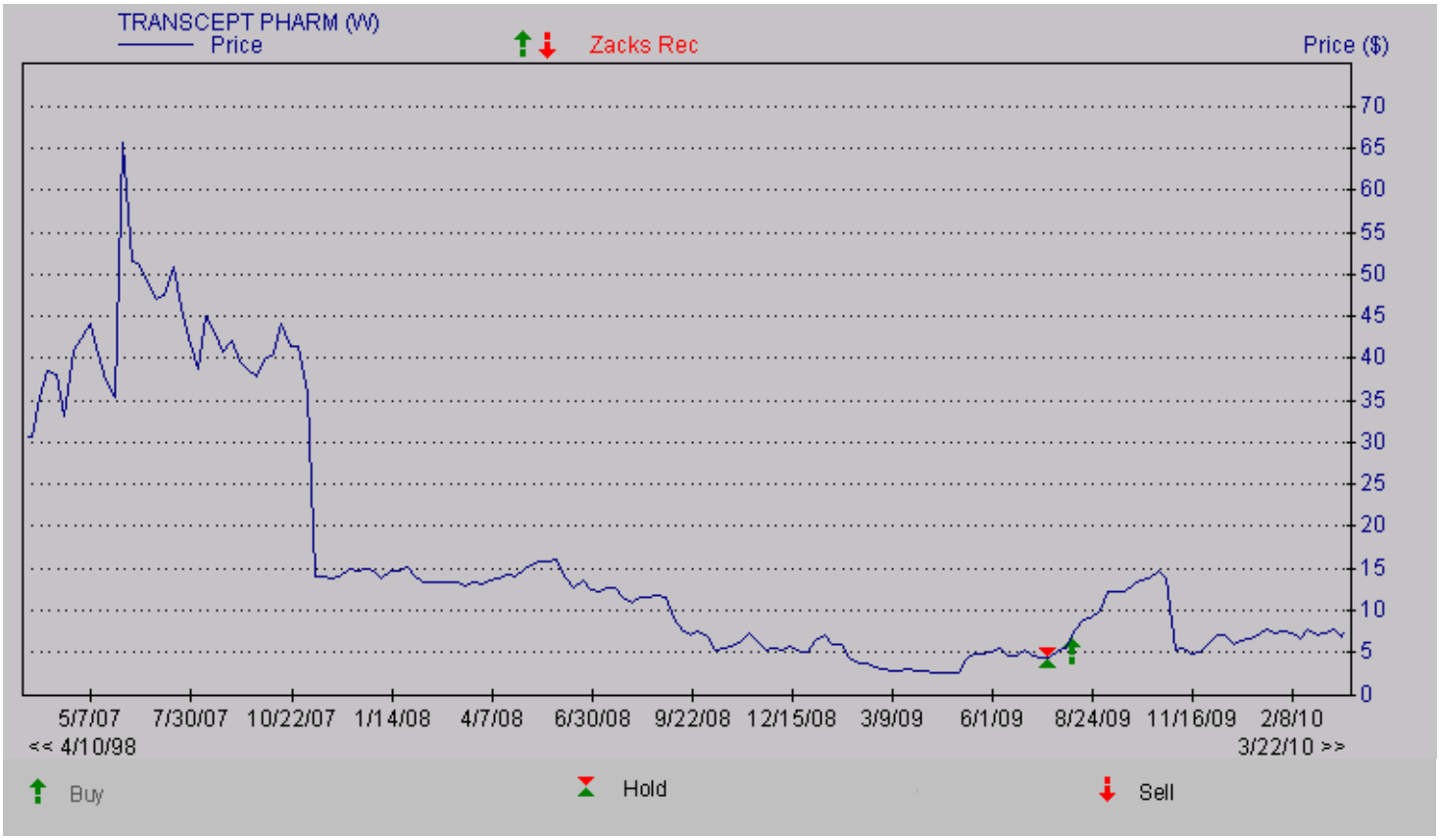
HISTORICAL ZACKS RECOMMENDATIONS



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