Zacks Equity Research

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Transcept Pharmaceuticals, Inc. (TSPT-NASDAQ)

TSPT: Meeting With FDA on Intermezzo Provides Guidance on Future Plans. Maintain Outperform Rating.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	08/10/2009
Current Price (01/21/10)	$6.95
Target Price	**$10.00**

UPDATE

On January 20, 2010, Transcept management met with the U.S. FDA to discuss the complete response letter issues last October on Intermezzo. We do not expect management to comment publically on the meeting until the final minutes have been issued. This is usually a 30 to 45 day process, putting a potential release from the company on the future plans for the drug sometime in late February 2010. However, 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. We are maintaining our positive rating on the stock.

SUMMARY DATA

52-Week High	**$15.12**
52-Week Low	**$2.80**
One-Year Return (%)	**27.17**
Beta	**2.49**
Average Daily Volume (sh)	**14,735**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$102**
Short Interest Ratio (days)	**3.48**
Institutional Ownership (%)	**20**
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 2009 Estimate	**N/A**
P/E using 2010 Estimate	**N/A**
Zacks Rank	**3**

Risk Level	**Average,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**94 of 136**

ZACKS ESTIMATES

Revenue
(millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2008	0 A	0 A	0 A	0 A	0 A
2009	0 A	0 A	2.1 A	3.1 E	5.2 E
2010					12.5 E
2011					46.1 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2008	-$1.99 A	-$1.71 A	-$1.42 A	-$1.93 A	-$7.03 A
2009	-$0.95 A	-$0.54 A	-$0.29 A	-$0.23 E	-$1.85 E
2010					-$1.16 E
2011					$0.05 E

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

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WHAT'S NEW

Transcept Meets With FDA To Discuss Intermezzo…

On January 20, 2010, Transcept management met with the U.S. FDA to discuss the complete response letter issued last October 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, would not present an unacceptable risk of next day driving ability (for additional details on the letter, see our November 17, 2009 report).

We do not expect management to comment publically on the meeting until the final minutes have been issued. This is usually a 30 to 45 day process, putting a potential release from the company on the future plans for the drug sometime in late February 2010. Management will probably release fiscal 2009 earnings in March 2010.

Based on our analysis of the complete response letter and discussions with management, our best guess is that the company will institute a radical re-design in packaging for Intermezzo. Quite simply, we expect that Transcept will package Intermezzo in a very similar fashion 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 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.



We expect that management at Transcept will also use the large size of the packet to include dosing information relating to when the product should be used on each pouch. This can include a chart or graph showing time of night and time to morning, simple graphics to remind the patient that they must be able to devote at least four hours to sleep after dosing. The good thing about the large pouch is that is also acts as a billboard / reminder to the patient that they have already dosed one Intermezzo so far that night and another tablet should not be taken. Although we note this never occurred in the phase III program. Management may also include a dosing wheel or sliding scale chart in each box that patients can use to determine when it is appropriate to take Intermezzo depending on when they would like to wake up the next morning.

Nothing suggested here is revolutionary. Nothing here is strange to the FDA. These are techniques that seem to be working for Merck with Maxalt and clearly attempt to answer the FDA's concern on misdosing. The FDA asked Transcept to address "methods to avoid" misdosing, and we believe this does the trick.

With respect to the potential for a driving study, we expect that this is something Transcept plans to initiate in the second quarter 2010. Assuming the meeting minutes come back in late February 2010, management will probably push forward with the design of the driving study in March. If all goes well, the trial should begin in April. 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.

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.

Maintaining 'Outperform' Rating – New Target is $10…

We are maintaining our positive rating on Transcept despite the setback. The stock is now trading around cash value. We are adjusting our target to $10 based on 20x our 2013 EPS estimate of $1.35. The company's financial position is solid and the partnership on Intermezzo should remain intact. We advise investors to let the selling play out, which may take another few weeks, and then either establish a position or average-down at this level.

PROJECTED FINANCIALS

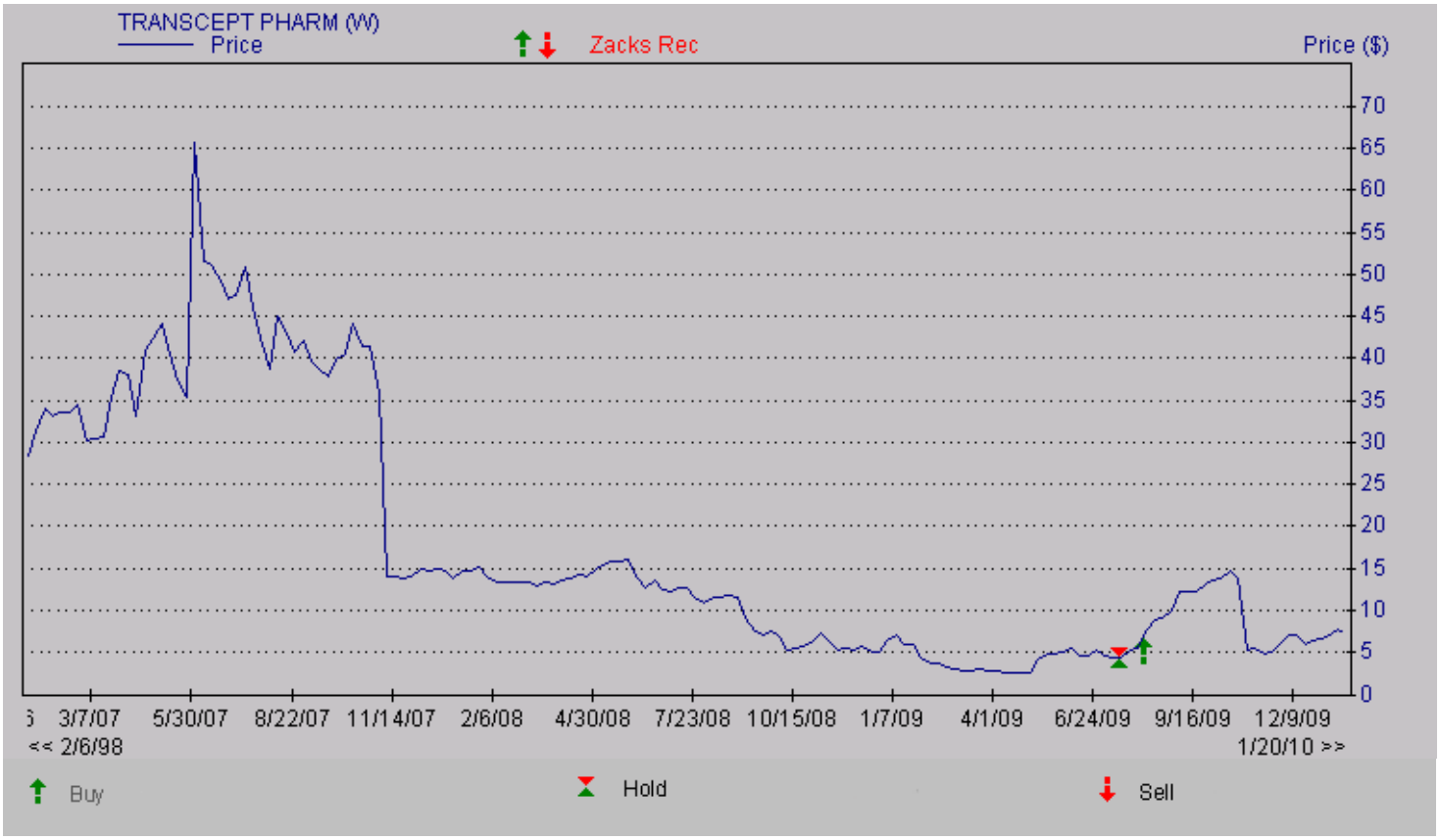
Transcept Pharmaceuticals, Inc.
Income Statement

	2008 A	Q1 A	Q2 A	Q3 A	Q4 E	2009 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**	**$0**	**$0**	**$2.1**	**$3.1**	**$5.2**	**$12.5**	**$27.3**	**$20.0**	**$20.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Total Revenues	**$0**	**$0**	**$0**	**$2.1**	**$3.1**	**$5.2**	**$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	$4.2	$5.0	$3.8	$4.0	$17.1	$17.5	$23.5	$25.0	$27.0
% SG&A	-	-	-	-	-	-	-	*65.3%*	*51.9%*	*38.4%*
R&D	$10.4	$2.2	$2.2	$2.1	$2.3	$8.9	$11.5	$12.5	$14.5	$16.0
% R&D	-	-	-	-	-	-	-	*34.7%*	*30.1%*	*22.7%*
Merger & Other Costs	$2.0	$2.2	$0	$0	$0	$2.2	$0	$0	$0	$0
Operating Income	($20.3)	($8.7)	($7.3)	($3.9)	($3.2)	($23.0)	($16.5)	($0.0)	$8.7	$27.3
Operating Margin	-	-	-	-	-	-	-	*0.0%*	*18.0%*	*38.9%*
Interest & Other Net	$0.3	$0.1	$0.2	$0.1	$0.1	$0.5	$0.5	$0.7	$0.6	$0.5
Pre-Tax Income	($20.0)	($8.5)	($7.1)	($3.8)	($3.1)	($22.5)	($16.0)	$0.7	$9.3	$27.8
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$0.9	$7.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*10.0%*	*25.0%*
Net Income	($20.0)	($8.5)	($7.1)	($3.8)	($3.1)	($22.5)	($16.0)	$0.7	$8.4	$20.9
YOY Growth	-	-	-	-	-	-	-	-	*1118.3%*	*149.5%*
Net Margin	-	-	-	-	-	-	-	*1.9%*	*17.4%*	*29.7%*
Reported EPS	**($7.03)**	**($0.95)**	**($0.54)**	**($0.29)**	**($0.23)**	**($1.85)**	**($1.16)**	**$0.05**	**$0.56**	**$1.35**
YOY Growth	-	-	-	-	-	-	-	-	*1077.7%*	*141.5%*
Shares Outstanding	2.8	9.0	13.1	13.2	13.4	12.2	13.8	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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