Zacks Equity Research

May 13, 2010
Jason Napodano, CFA
312-265-9421
jnapodano@zacks.com

www.zacks.com
111 North Canal Street, Chicago, IL 60606

Transcept Pharmaceuticals, Inc. (TSPT-NASDAQ)

TSPT: Transcept To Start Driving Study on Intermezzo Shortly…NDA Late 2010…

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 November 2010. That puts an action date in May 2011. With over $80 million in cash still on the books and a market value of only $127 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 (05/12/10)	$9.25
Target Price	**$12.00**

SUMMARY DATA

52-Week High	**$15.12**
52-Week Low	**$4.56**
One-Year Return (%)	**85.80**
Beta	**2.58**
Average Daily Volume (sh)	**26,724**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$124**
Short Interest Ratio (days)	**3.28**
Institutional Ownership (%)	**4**
Insider Ownership (%)	**42**
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	**2**

Risk Level	**Average,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**
Zacks Rank in Industry	**22 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 A	3.1 E	3.1 E	3.1 E	12.5 E
2011					34.8 E
2012					46.1 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	-$0.14 A	-$0.15 E	-$0.18 E	-$0.19 E	-$0.67 E
2011					$0.80 E
2012					$0.87 E

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

© Copyright 2010, Zacks Investment Research. All Rights Reserved.

WHAT'S NEW

Financial Review…

On May 12, 2010, Transcept Pharmaceutical reported financial results for the first quarter 2010. Total revenues in the first quarter were $3.125 million and were comprised solely of recognition of a portion of the $25 million non-refundable license fee received from Purdue in connection with the collaboration agreement for commercialization of Intermezzo in the U.S. Transcept is recognizing the $25 million license fee over a 24-month period that commenced in August 2009. Net loss for the first quarter totaled $1.8 million, or $0.14 per share. Both revenues and EPS were in-line with our expectations. Transcept exited the first quarter ended March 31, 2010 with $83.1 million in cash and investments – or approximately $6.25 per share. We believe this substantial cash balance provides enough runway to see the company through the approval of Intermezzo in 2011, as well as investment protection on the downside should the U.S. FDA further delay the approval.

Driving Study To Begin Late Q2-2010…

As a reminder, in the complete response letter received in October 2009 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. These concerns were irritated at the company's meeting with the FDA in January 2010. Therefore, to further understand the safety of dosing Intermezzo in the middle of the night, Transcept will 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.

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 40 patients in 4-arms (Intermezzo dosed at T-3 hours, Intermezzo doses at T-4 hours, placebo, and an active control (zopiclone dosed at T-8 hours) in a cross-over design. The trial will take place at Maastricht University in The Netherlands, a leading center of research on the effects of drugs and alcohol on driving performance. The primary endpoint of the study will be a measure of standard deviation of lateral position over a 100 kilometer public highway route. Any significant increase in this measure, versus placebo, would reflect impaired driving.

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 November 2010. Assuming a standard (class-II) review of six-months, we could be looking at FDA action in Intermezzo around May 2011. Approval in May 2011 will be 11 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 May 2011 Transcept loses out 11 months, or $22 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 $18 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 not earlier than February 2025. As a reminder, Transcept will earn a $10 million milestone when the first patent is listed in the FDA's Orange book. Management does have another family of patents that they are in the middle of prosecuting right now that relate to methods of use of zolpidem in the treatment of middle of the night insomnia. These would also expire in the 2025 / 2026 timeframe.

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…

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 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 $127 million, just $44 million above the cash on the balance sheet of $39 million at year end 2009. This undervalues the company in our view. In March 2010 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 $44 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

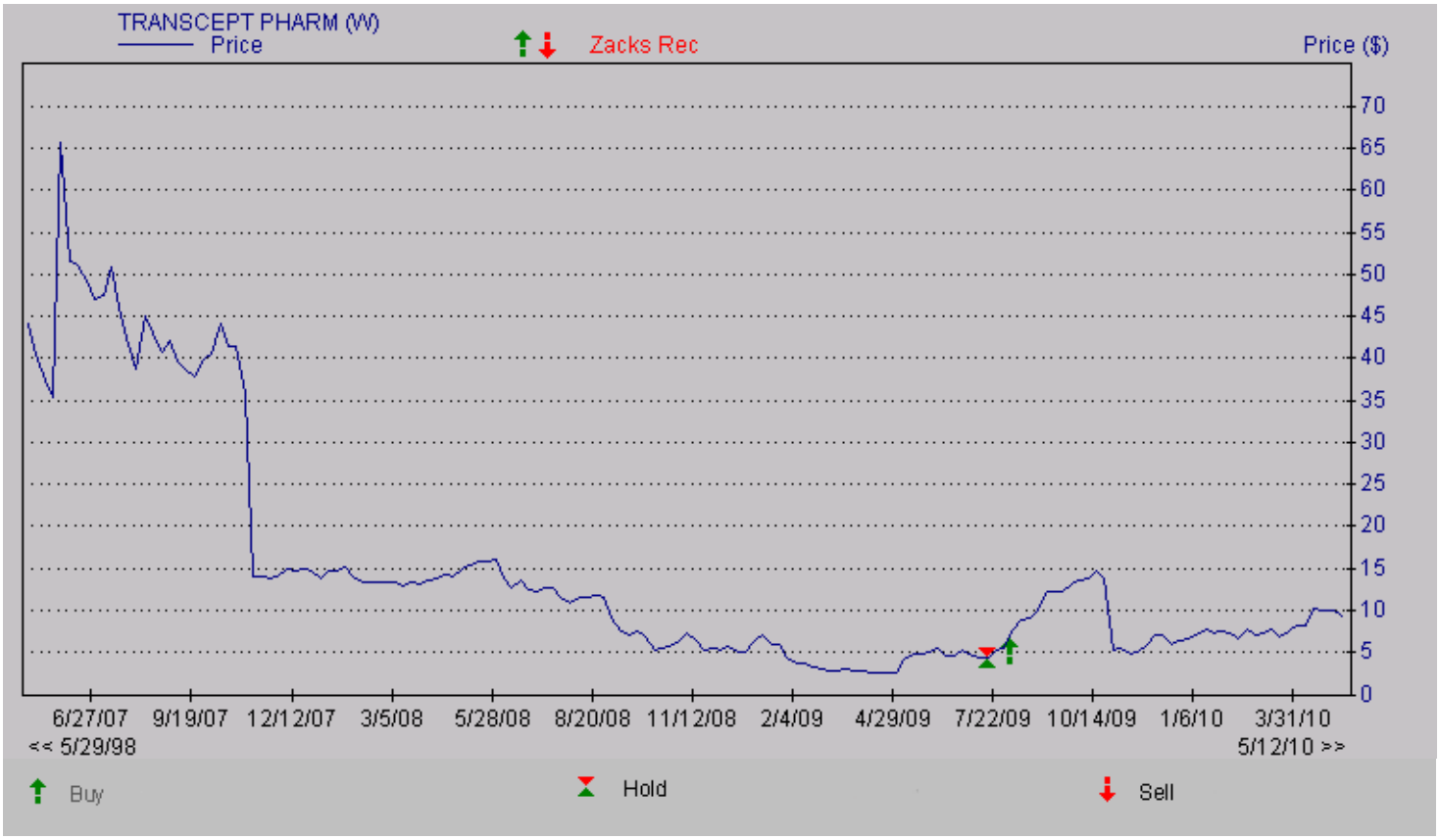
Transcept Pharmaceuticals, Inc.
Income Statement

	2008 A	2009 A	Q1 A	Q2 E	Q3 E	Q4 E	2010 E	2011 E	2012 E	2013 E
Intermezzo (US Sales)	$0	$0	$0	$0	$0	$0	$0	$32.0	$88.0	$148.0
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**	**$7.5**	**$26.1**	**$48.0**
YOY Growth	-	-	-	-	-	-	-	-	*246.8%*	*84.0%*
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**	**$34.8**	**$46.1**	**$68.0**
YOY Growth	-	-	-	-	-	-	*140.0%*	*178.5%*	*32.4%*	*47.5%*
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	$2.6	$2.7	$3.0	$3.3	$11.6	$13.5	$20.5	$23.5
% SG&A	-	*308.0%*	*83.3%*	*86.4%*	*96.0%*	*105.6%*	*92.8%*	*38.8%*	*44.5%*	*34.6%*
R&D	$10.4	$9.0	$2.4	$2.5	$2.6	$2.4	$9.9	$10.0	$11.5	$12.5
% R&D	-	*172.9%*	*75.5%*	*80.0%*	*83.2%*	*76.8%*	*78.9%*	*28.7%*	*25.0%*	*18.4%*
Merger & Other Costs	$2.0	$2.2	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($20.3)	($22.1)	($1.8)	($2.1)	($2.5)	($2.6)	($9.0)	$11.3	$14.1	$32.0
Operating Margin	-	-	-	-	-	-	-	*32.5%*	*30.6%*	*47.0%*
Interest & Other Net	$0.3	$0.3	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	$0.3	$0.4	$0.5
Pre-Tax Income	($20.0)	($21.8)	($1.8)	($2.1)	($2.5)	($2.6)	($9.0)	$11.6	$14.5	$32.5
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$1.4	$8.1
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*10.0%*	*25.0%*
Net Income	($20.0)	($21.8)	($1.8)	($2.1)	($2.5)	($2.6)	($9.0)	$11.6	$13.0	$24.4
YOY Growth	-	-	-	-	-	-	-	-	*12.2%*	*86.9%*
Net Margin	-	-	-	-	-	-	-	*33.4%*	*28.3%*	*35.8%*
Reported EPS	**($7.03)**	**($1.79)**	**($0.14)**	**($0.15)**	**($0.18)**	**($0.19)**	**($0.67)**	**$0.80**	**$0.87**	**$1.57**
YOY Growth	-	-	-	-	-	-	-	-	*8.5%*	*80.9%*
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*

© Copyright 2010, Zacks Investment Research. All Rights Reserved.

HISTORICAL ZACKS RECOMMENDATIONS



DISCLOSURES

The analysts contributing to this report do not hold any shares of TSPT. Zacks EPS and revenue forecasts are not consensus forecasts. Zacks has or seeks to have a business relationship with the securities listed in this report. Additionally, the analysts contributing to this report certify that the views expressed herein accurately reflect the analysts' personal views as to the subject securities and issuers. Zacks certifies that no part of the analysts' compensation was, is, or will be, directly or indirectly, related to the specific recommendation or views expressed by the analyst in the report. Additional information on the securities mentioned in this report is available upon request. This report is based on data obtained from sources we believe to be reliable, but is not guaranteed as to accuracy and does not purport to be complete. Because of individual objectives, the report should not be construed as advice designed to meet the particular investment needs of any investor. Any opinions expressed herein are subject to change. This report is not to be construed as an offer or the solicitation of an offer to buy or sell the securities herein mentioned. Zacks or its officers, employees or customers may have a position long or short in the securities mentioned and buy or sell the securities from time to time. Zacks uses the following rating system for the securities it covers. **Outperform**- Zacks expects that the subject company will outperform the broader U.S. equity market over the next one to two quarters. **Neutral**- Zacks expects that the company will perform in line with the broader U.S. equity market over the next one to two quarters. **Underperform**- Zacks expects the company will under perform the broader U.S. Equity market over the next one to two quarters. The current distribution of Zacks Ratings is as follows on the 988 companies covered: Outperform- 13.4%, Neutral- 78.8%, Underperform – 7.2%. Data is as of midnight on the business day immediately prior to this publication.

© Copyright 2010, Zacks Investment Research. All Rights Reserved.