Zacks Equity Research

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Transcept Pharmaceuticals, Inc. (TSPT-NASDAQ)

TSPT: Update on Intermezzo and The Pipeline…

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 in early 2011. That puts an action date in July 2011. With over $80 million in cash still on the books and a market value of only $125 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 (06/09/10)	$9.32
Target Price	**$12.00**

SUMMARY DATA

52-Week High	**$15.12**
52-Week Low	**$4.56**
One-Year Return (%)	**71.82**
Beta	**2.33**
Average Daily Volume (sh)	**30,774**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$127**
Short Interest Ratio (days)	**2.09**
Institutional Ownership (%)	**10**
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	**71 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					33.4 E
2012					39.3 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					$0.70 E
2012					$0.46 E

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

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WHAT'S NEW

Driving Study Begins Enrollment…

Management has finalized its plans for the Highway Driving Study. As a reminder, in the complete response letter received in October 2009 the FDA 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 reiterated at the company's meeting with the FDA in January 2010. Transcept has begun this study in early June 2010 to assess the effect of Intermezzo on driving ability beginning at approximately three hours and four hours post-dosing.

Transcept will 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 early in the first quarter 2011. Assuming a standard (class-II) review of six-months, we could be looking at FDA action in Intermezzo around June / July 2011. Approval in June / July 2011 will be roughly year 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 12 months, or $24 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 $16 million. This is on top of the $25 million upfront Transcept received in August 2009, and an additional $90 million in achievement of certain patient milestones and net sales targets, including a $10 million milestone payment for the first formulation patent listed in the FDA's Orange Book.

We note that Transcept receives a double-digit royalty up to mid 20% on net sales at Purdue. Transcept also has a co-promotion option where the company can earn an additional double digit royalty on sales into the psychiatric market. The option to co-promote Intermezzo becomes available as early as the first anniversary after the primary care launch by Purdue.

Looking For Pipeline Expansion…

The option to co-promote Intermezzo into the psychiatric market becomes particularly interesting for Transcept in 2012 and beyond because of the company's early-stage development pipeline. This includes TO-2061, a low-dose ondansetron augmentation under development for use as an adjunctive therapy in adult patients with treatment-resistant obsessive compulsive disorder (TR-OCD). TR-OCD is an area where there are no FDA-approved treatment options for patients. When a patient fails first-line SSRI therapy, psychiatrists often look to augment therapy with off-label atypical antipsychotics. This is a rather poor option. Nearly 70% show no improvement with atypicals. In fact, most only see added adverse side-effects, including weight gain and metabolic disorder commonly associated with these drugs.

Transcept has conducted two positive pilot studies characterizing the potential for TO-2061 in TR-OCD patients. The first study (Pilot Study A) was conducted in 14 patients who had failed first-line SSRI. These patients received TO-2061 plus an atypical antipsychotic. The second study (Pilot Study B) was conducted in 21 patients who had failed first-line SSRI. These patients received TO-2061 alone. Results from both studies show clinically meaningful improvement in TR-OCD symptoms upon completion. The results also show that TO-2061 (low-dose ondansetron) was well tolerated with no dropouts due to adverse events.

An IND has been filed and accepted by the U.S. FDA in the second quarter 2010. Transcept will follow a 505(b)(2) pathway for TO-2061, relying on the substantial preclinical safety data on ondansetron (sold as Zofran for the treatment of chemotherapy induced nausea and vomiting by GlaxoSmithKline since January 1991). The next step for Transcept is to conduct a PK and dosage form study. This should begin later in 2010, with completion planned for the first half of 2011. Following completion of the PK analysis, management plans a phase II proof-of-concept program to begin in late 2011.

INVESTMENT THESIS

Intermezzo Looks To Fill A Much Needed Void…

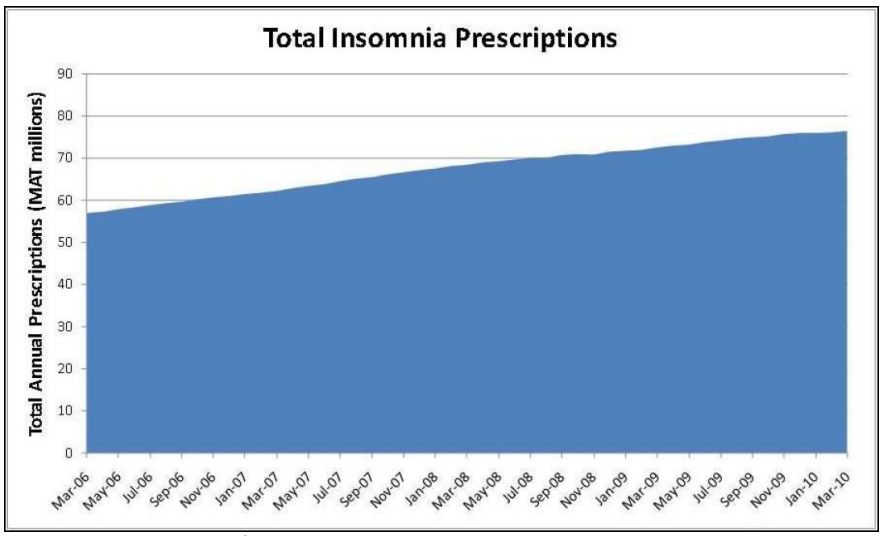
Insomnia remains a significant problem in the U.S. and Europe, and as such, there exists an attractive market opportunity for the launch of a new pharmaceutical product with differentiating characteristics. We estimate that nearly 70 million American adults (30% prevalence rate) are affected by some 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, waking up not feeling refreshed, or a combination of all three. Approximately a third of insomnia patients report nocturnal awakenings with difficulty returning to sleep. In greater than 75% 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.

We see a significant void in the insomnia market for that 35% of the adult population that suffer from nocturnal awakenings. In fact, according to the Stanford Sleep Epidemiology Research Center, only around 11% of these patients seek physician consultation about their insomnia. Perhaps this is due to the lack of effective treatment options. Ambien and generic zolpidem are approved for sleep onset only, and are recommended for use only when the patient can devote 7 to 8 hours to sleep. The current Ambien label precludes middle-of-the-night (MOTN) dosing. Both Lunesta and Ambien CR are approved for sleep onset and maintenance. The drugs are designed to put you to sleep and keep you asleep all night long. However, data shows that over half the patients that take Lunesta and Ambien CR still report 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. Chronic patients typically suffer from nocturnal awakenings 3 to 4 times a week. The proposed PRN dosing for Intermezzo eliminates necessary dosing of Ambien CR or Lunesta each night, and eliminates potentially dangerous dosing of Ambien or generic zolpidem in the middle of the night.

The sublingual tablet dissolves in less than 2 minutes, without water, and puts patients back to sleep quickly. Sleep lab clinical results show an average of 14 minutes for onset at the standard 3.5mg dose. Plus, in two phase III studies, Transcept observed no significant next day residual effects compared to placebo.

We think this presents a meaningful opportunity for Transcept and commercialization partner, Purdue Pharma. The insomnia market is large and still growing at an annual prescription rate of 5% CAGR. Nearly 90% of patients that suffer from nocturnal awakenings go untreated. Generic zolpidem, which has completely stalled new prescription share gains for Lunesta and Ambien CR in the onset and maintenance category of the market, has had little penetration with nocturnal awakenings. With Purdue's strong presences in the primary care market, we believe Intermezzo can capture meaningful market share here.



Source: Transcept Pharma, Inc.

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…75% 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% * 75% * 11% * 10% * 150 pills/year * $5 per pill ~ $500 million

By 2014, we think Intermezzo can capture about 1/2 of this peak sales opportunity. We think the European market is probably about similar in size of the U.S. market, only pricing in Europe is only 20% of the U.S. price. Management plans to seek an Ex-U.S. partnership for Intermezzo perhaps in 2011. Upside to this $500 million peak U.S. sales figure could come from increasing any of the above components, with the most likely being penetration and market share. 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.

Expanding The Pipeline With TO-2061

Transcept is currently in early stage development with TO-2061, a low-dose ondansetron augmentation for potential use as an adjunctive therapy in adult patients with treatment-resistant obsessive compulsive disorder (TR-OCD). Ondansetron, a 5-HT_3 antagonist, was approved in January 1991 under the brand name Zofran at GlaxoSmithKline for the treatment and prevention of chemotherapy-induced nausea and vomiting. It is now available as a generic. Similar to SSRIs, ondansetron affects serotonin pathways and may enhance SSRI effects on OCD symptoms. The drug also reduces dopaminergic activity, similar to atypical antipsychotics, and may inhibit repetitive behavior by down-regulating dopamine.

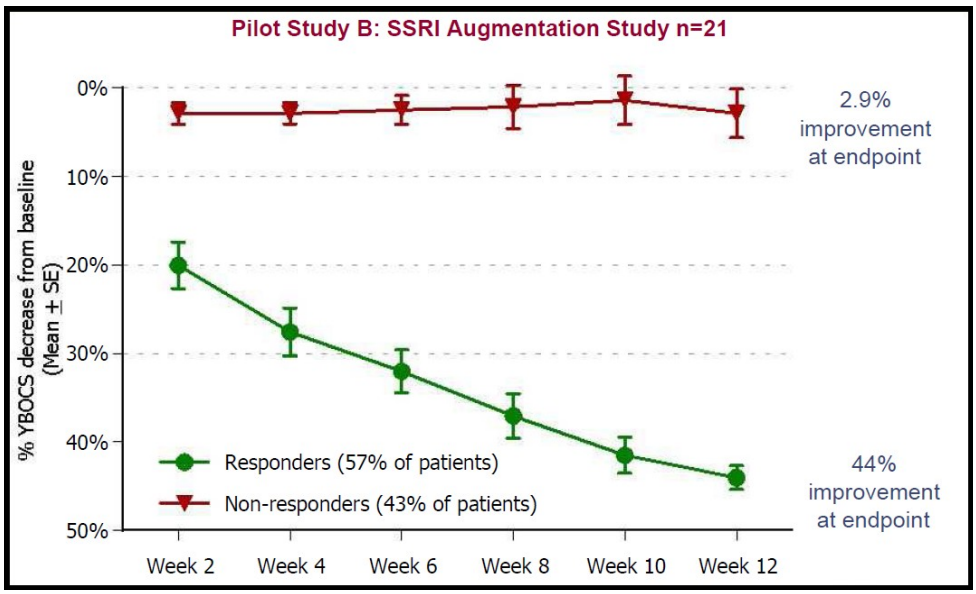
TR-OCD is an area where there are no FDA-approved treatment options for patients. First-line therapy for OCD includes treatment with selective serotonin reuptake inhibitors (SSRI), including Prozac, Luvox, Paxil, or Zoloft. Unfortunately, 40% to 60% of patients will fail this within the first few months. When a patient fails first-line SSRI therapy, psychiatrists often look to augment therapy with off-label atypical antipsychotics. This is a rather poor option. Nearly 70% show no improvement signs with atypicals. In fact, most only see added adverse side-effects, including weight gain and metabolic disorder commonly associated with these drugs.

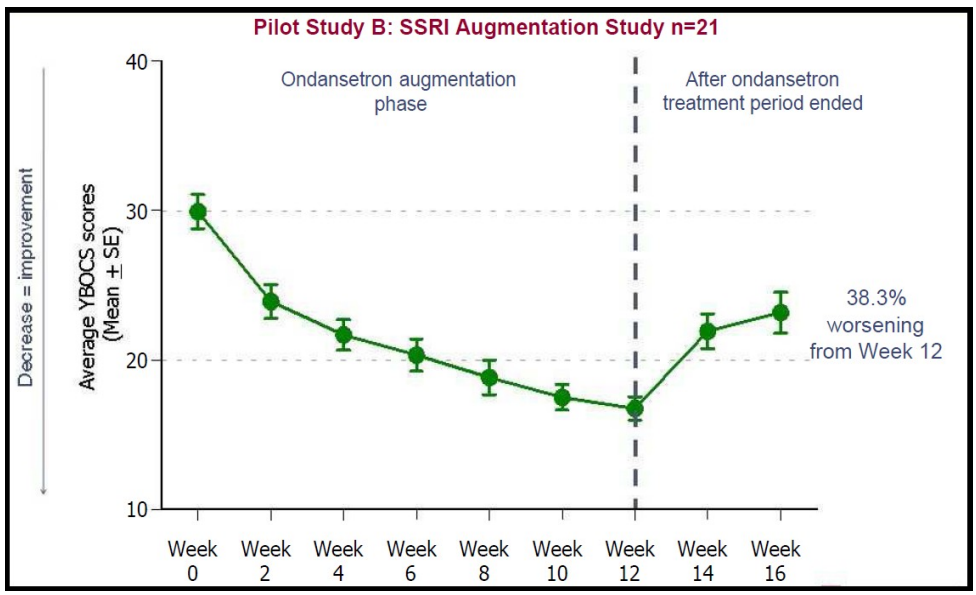
Transcept has conducted two pilot studies characterizing the potential of low-dose ondansetron in TR-OCD:

- Study A: Ondansetron augmentation in patients who responded poorly to at least 12 weeks of SSRI treatment combined with an atypical antipsychotic (n=14).

- Study B: Ondansetron augmentation in patients who responded poorly to at least 12 weeks of SSRI treatment alone (n=21).

Results show that patients resistant to multiple treatments improved when ondansetron was added. Ondansetron augmentation in SSRI treatment-resistant patients produced clinically meaningful improvement in OCD symptoms. Ondansetron improved the symptoms in >50% of patients who responded poorly to SSRI treatment. And, 8 of the 12 responders relapsed within four weeks after the ondansetron treatment period was stopped. Finally, low-dose ondansetron was well tolerated in both studies, with no dropouts due to adverse events.





An IND has been filed and accepted by the U.S. FDA in the second quarter 2010. Transcept will follow a 505(b)(2) pathway for TO-2061, relying on the substantial preclinical safety data on Zofran by GlaxoSmithKline. The next step for Transcept is to conduct a PK and dosage form study. Typical doses of Zofran for CINV are 16mg to 24mg per day. The dose for TO-2061 will be substantially less. This should begin later in 2010, with completion planned for the first half of 2011.

Following completion of the PK analysis, management plans a phase II proof-of-concept program to begin in late 2011. The planned phase II program will be well-designed (double-blind, placebo-controlled) and large enough (at roughly 150 patients), that if successful, management could potentially use the data as one of the two required pivotal phase III studies for NDA submission. Top-line results from the planned phase II are expected in the second half of 2012. Commercializing TO-2061 presents an attractive opportunity to leverage the co-promotional agreement with Purdue pharma on Intermezzo to psychiatrist. By 2014, Transcept could be promoting both Intermezzo and TO-2061 with a relatively small specialty field force. We estimate the costs of developing TO-2061 through proof-of-concept are less than $10 million. At the end of the first quarter (March 31, 2010), Transcept held over $83 million in cash and investments.

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 $125 million, just $42 million above the cash on the balance sheet of $83 million at the end of March 2010. 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 $220 million. In our view, the market is applying a similar steep discount to Transcept, with an enterprise value of only $42 million less the cash balance. Once Intermezzo is approved in about a year, we would expect a similar rapid revaluation to significantly higher levels. The future successful development of TO-2061 for TR-OCD represents further upside to the story.

PROJECTED FINANCIALS

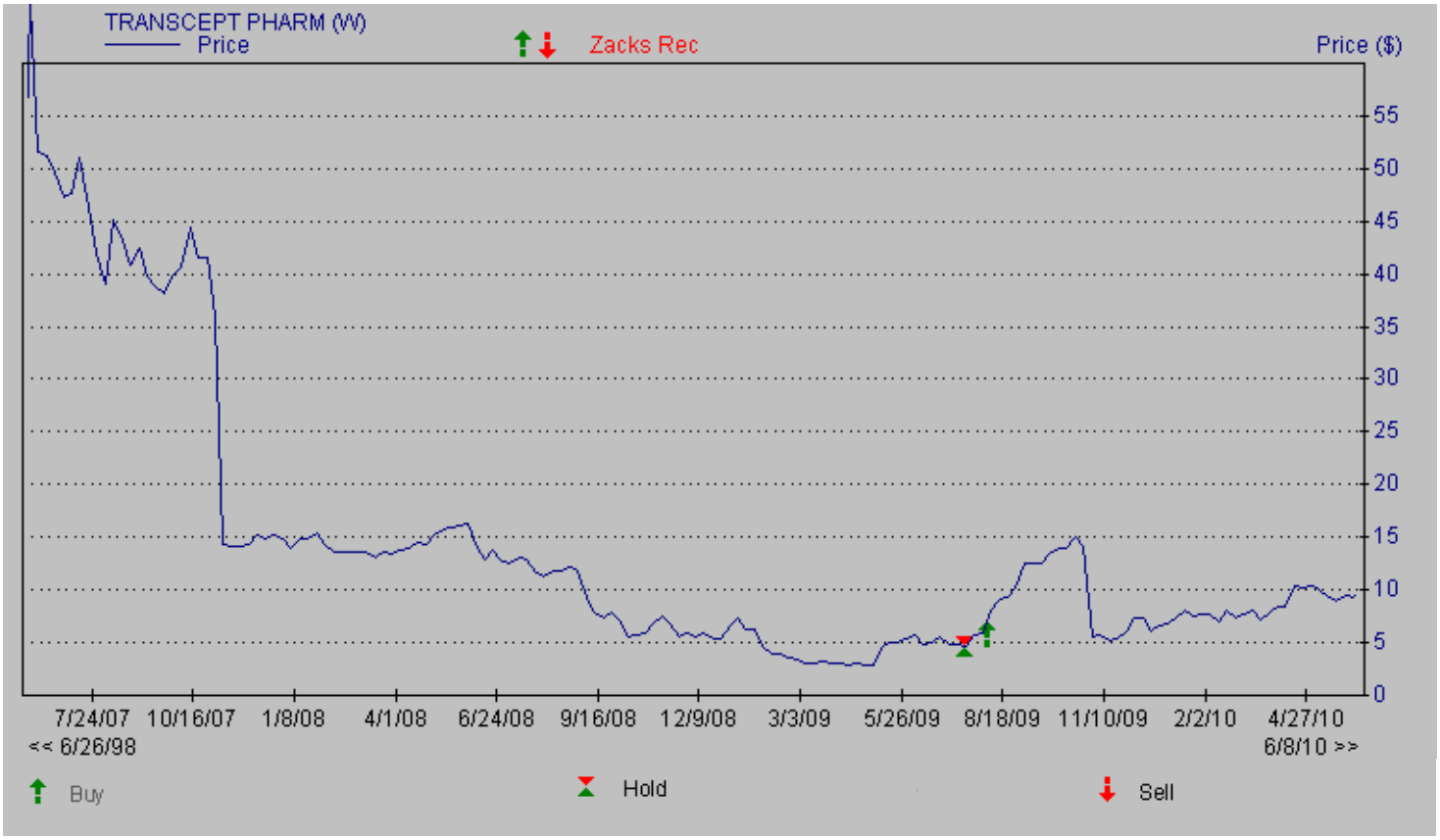
Transcept Pharmaceuticals, Inc.
Income Statement

	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	$26.0	$82.0	$142.0
Intermezzo (Ex-US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$15.0
Intermezzo Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$6.1**	**$19.3**	**$35.2**
YOY Growth	-	-	-	-	-	-	-	-	*215.4%*	*82.5%*
Collaborations / Milestones	**$0**	**$5.2**	**$3.1**	**$3.1**	**$3.1**	**$3.1**	**$12.5**	**$27.3**	**$20.0**	**$20.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
TO-2061	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Total Revenues	**$0**	**$5.2**	**$3.1**	**$3.1**	**$3.1**	**$3.1**	**$12.5**	**$33.4**	**$39.3**	**$55.2**
YOY Growth	-	-	-	-	-	-	*140.0%*	*167.2%*	*17.6%*	*40.5%*
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%*	*40.4%*	*52.2%*	*42.6%*
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%*	*29.9%*	*29.3%*	*22.7%*
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)	$9.9	$7.3	$19.2
Operating Margin	-	-	-	-	-	-	-	*29.6%*	*18.5%*	*34.7%*
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)	$10.2	$7.7	$19.7
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$0.8	$4.9
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)	$10.2	$6.9	$14.8
YOY Growth	-	-	-	-	-	-	-	-	*-32.3%*	*113.7%*
Net Margin	-	-	-	-	-	-	-	*30.5%*	*17.6%*	*26.7%*
Reported EPS	**($7.03)**	**($1.79)**	**($0.14)**	**($0.15)**	**($0.18)**	**($0.19)**	**($0.67)**	**$0.70**	**$0.46**	**$0.95**
YOY Growth	-	-	-	-	-	-	-	-	*-34.6%*	*106.8%*
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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