Zacks Equity Research

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Transcept Pharmaceuticals, Inc. (TSPT-NASDAQ)

TSPT: Meeting With Management Keeps Us Optimistic on Intermezzo…

UPDATE

We remain optimistic on the approval of Intermezzo later in 2011. In our view, the product fills a much needed void in the insomnia space. Ambien and Lunesta 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 labels preclude middle-of-the-night (MOTN) dosing. Despite this, epidemiology studies show significant off-label use these drugs during the MOTN. Market research shows that physicians are even prescribing and recommending Ambien and Lunesta for this potentially dangerous use. We view the approval of Intermezzo as an excellent opportunity for the FDA to offer physicians an approved and safer alternative.

Current Recommendation	**Outperform**
Prior Recommendation	Neutral
Date of Last Change	08/10/2009
Current Price (01/13/11)	$9.04
Target Price	**$12.00**

SUMMARY DATA

52-Week High	**$10.84**
52-Week Low	**$5.96**
One-Year Return (%)	**8.52**
Beta	**2.16**
Average Daily Volume (sh)	**19,066**
Shares Outstanding (mil)	**13**
Market Capitalization ($mil)	**$120**
Short Interest Ratio (days)	**5.86**
Institutional Ownership (%)	**14**
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	**36 of 141**

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 A	3.1 A	3.1 E	12.5 E
2011	3.1 E	3.1 E	20.5 E	7.8 E	34.6 E
2012					36.9 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 A	-$0.21 A	-$0.19 E	-$0.69 E
2011	-$0.17 E	-$0.17 E	$1.08 E	$0.12 E	$0.85 E
2012					$0.41 E

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

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WHAT'S NEW

Meeting With Management

On January 10, 2011 we sat down with Glenn Oclassen, CEO and Tom Soloway, CFO, for an update on the current business plans at Transcept. Management reiterated its previous guidance that the re-filing of the Intermezzo NDA will take place in the first quarter 2011. We are tentatively modeling the re-file in February, which would put potential FDA action based on a class-2 response in August 2011. The proposed indication for approval will be: Intermezzo is indication for use as needed for the treatment of insomnia when a middle of the night awakening is followed by difficulty returning to sleep."

Approval in August 2011 will result in a $6 million milestone from Purdue Pharma. Approval will also finalize the IP transfer to Purdue resulting in an additional $10 million milestone payment. The patent for Intermezzo has been listed in the FDA's Orange Book and will become active upon approval. We've accounting for a total of $16 million in milestone in the third quarter 2011. Transcept will receive a double-digit royalty up to mid 20% on net sales in the U.S. There are an additional $80 million in sale-related milestone that Transcept can earn during commercialization. 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 on the first anniversary after the primary care launch by Purdue. We fully expect Transcept to exercise this option in August / September 2012.

Besides the obvious focus on re-filing the Intermezzo NDA, management is also working on initiating a phase II program with TO-2061, now called Setrodon (ultra low dose ondansetron), in February 2011. We discuss this program below.

INVESTMENT THESIS

Driving Study Confirm Intermezzo Safety

In October 2010, Transcept released preliminary data from its highway driving study. The study was a double-blind, randomized, placebo-controlled, four-way crossover study of 40 healthy volunteers designed to evaluate the safety profile of Intermezzo with regard to next morning driving. The study evaluated standard deviation of lateral position (SDLP) in a highway driving lane, a surrogate measure for driving performance, as subjects drove an automobile 100 km, or 62 miles, on a public highway under normal traffic conditions for approximately one hour, and took place at the Maastricht University in The Netherlands, a leading center of research on the effects of drugs and alcohol on driving performance.

Subjects performed test drives on placebo, 7.5mg zopiclone as a positive control taken at bedtime 9 hours before driving, 3.5mg Intermezzo taken 3 hours before driving, and 3.5 mg Intermezzo taken 4 hours before driving. The 4 hours post dose is the proposed label for the commercial product. Management included data from patients at 3 hours post-dose to characterize the risk profile of Intermezzo and provide both physicians and patients with important safety information regarding next day driving ability.

One important aspect to note on the design of the trial is that the driving occurred exactly 3 hours and 4 hours post-dose. Subjects were woken up 45 minutes before actual driving occurred, meaning patients tested at 4 hours actually only slept for just over 3 hours when factoring in 10 minutes to fall asleep after dosing and 45 minutes of being awake before getting in the car. The proposed Intermezzo label will instruct patients to devote a full 4 hours to sleep, which means driving is not expected to occur for approximately 5 hours post dose.

Based on a review of the published literature, an SDLP change of 2.5 cm was specified in the protocol as the primary threshold of impairment for the purpose of performing the statistical analyses. For reference, a 0.05% blood alcohol concentration has been associated with a change in SDLP of 2.4 cm, and a blood level of 0.08% has been associated with a mean change in SDLP of 4.2 cm (Brookhuis, Human Psychopharmacology: Clinical and Experimental, Vol. 13, 1998). Management also assessed active drug versus placebo changes in SDLP at 20 different thresholds ranging from 1.75 cm up to 6.5 cm.

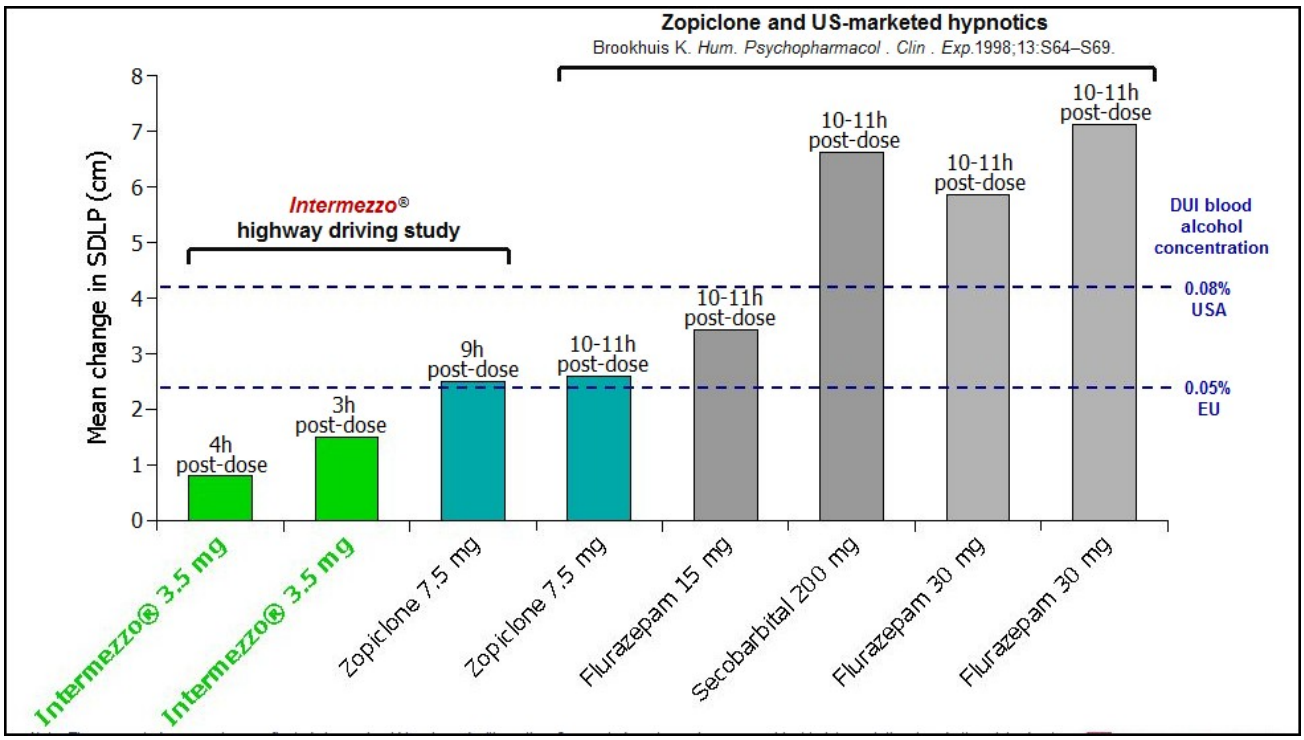
In March 2010, the FDA informed Transcept that the statistical methodology proposed by Transcept, a symmetry analysis, was a reasonable approach to measure potential next morning driving impairment. The symmetry analysis employed by management provides greater sensitivity for small changes in SDLP that would have otherwise been masked by a simple mean change analysis.

…The Data…

	Effect on SDLP At Threshold	Mean Difference From Placebo In SDLP
Placebo	N/S	-
3.5mg Intermezzo @ 4 hrs	N/S	0.8 cm
3.5mg Intermezzo @ 3 hrs	1.75cm to 4.0cm	1.5 cm
7.5mg zopiclone @ 9 hrs	1.75cm to 5.5cm	2.5 cm

It is important to note that this was not a standard efficacy protocol. Transcept was looking for signs of next day residual effect on driving ability. SDLP is a measure of variability in lane position and there is no commonly accepted change in SDLP that identifies a driver as being impaired. As such, Transcept compared Intermezzo to a placebo (negative control) and zopiclone (positive control). The data show no statistically significant effect on next day driving ability at any threshold tested for patients taking 3.5mg Intermezzo 4 hours post-dose. The mean difference in SDLP from placebo was only 0.8 cm. Signs of impairment were evident for patients taking Intermezzo at 3 hours post dose; however, this impairment was meaningfully less than the positive control of 7.5mg zopiclone at 9 hours post dose.

Below is a graphical representation of the data comparing Transcept's driving study to positive controls and other approved hypnotic drugs known to cause next-day residual driving issues:



Our Conclusion: In all practical sense, 3.5mg Intermezzo at 4 hours post dose behaved statistically non-inferior to the placebo, and was statistically superior to 7.5mg zopiclone. The significant effects of other approved medications such as zopiclone, flurazepam, and secobarbital are clearly evident in these types of studies.

We believe Transcept has run a well-designed trial that answered the key question address by the U.S. FDA in the complete response letter from October 2009 in reference to next day driving ability. Further analysis of the highway driving study will presented and/or published most likely following FDA action. However, based on these preliminary results, we are confident in Intermezzo's safety when used on label.

We note that in past approvals for CNS-active drugs, including hypnotics, opiates, anxiolytics, antidepressants and antihistamines, the FDA has acknowledged potential effects on driving and typically agreed to labeling language that relies upon a patient's self-assessment of how they react to a particular drug and their ability to drive safely.

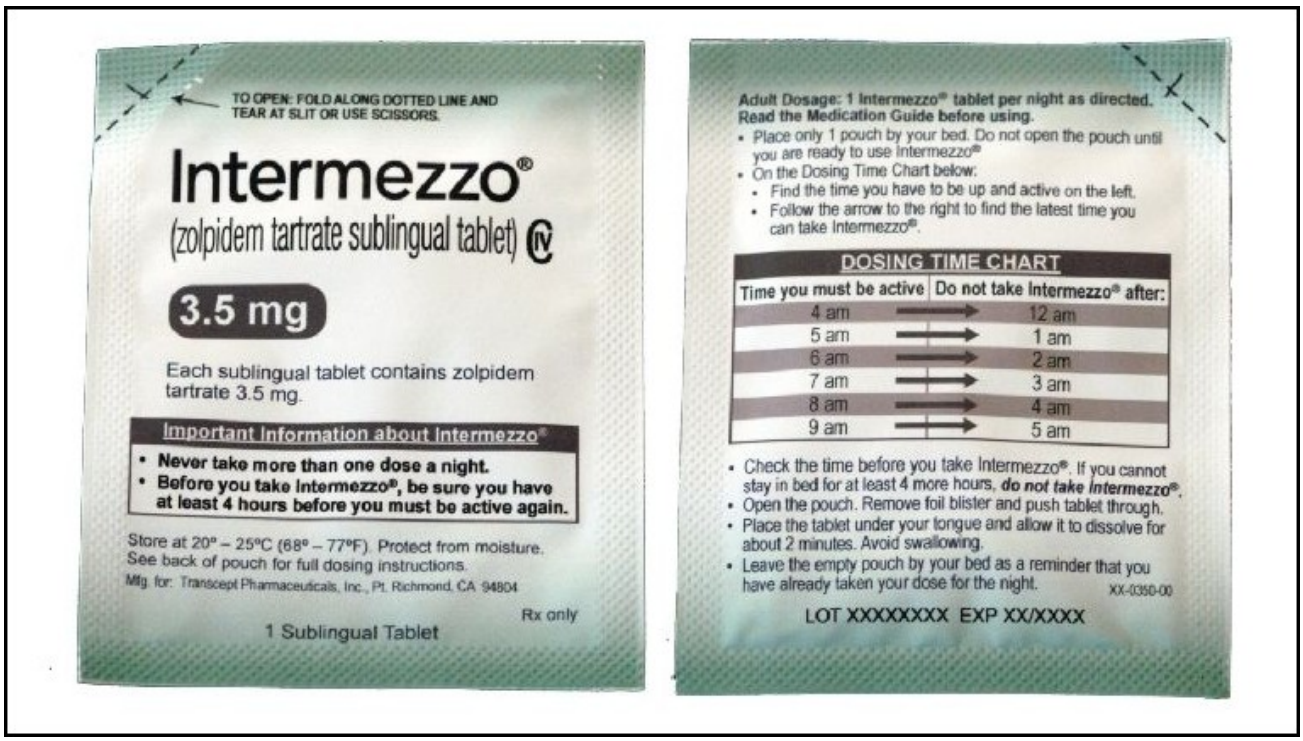
Additional Concerns Previously Addressed

The complete response letter received in October 2009 address two additional concerns:

The first involved inadvertent re-dosing in a single night, where a patient might awaken, take a dose of Intermezzo to help them return to sleep, and then reawaken later in the night and re-dose, having forgotten that they took the first dose. To address the re-dosing issue, management has proposed to the U.S. FDA that the company employ a bedside unit-dose packaging system. This consists of a single dose of Intermezzo sealed inside a child resistant pouch that measures approximately 3 by 4 inches. Patients will be instructed to keep their box of 30 pouches in the medicine cabinet, but at night, prior to bedtime, place a single pouch by their bedside. If they need Intermezzo in the middle of the night, they tear open the pouch, take a dose and leave the emptied pouch by their bed. The used package then serves as a strong reminder to patients, if they should reawaken, that they have already taken their medication. Management has discussed this revised packaging strategy with the FDA and they have agreed that it appears to decrease concerns about the risk of inadvertently re-dosing Intermezzo in a single night. On an interesting side note, inadvertent double-dosing never occurring during the 82-patient phase III clinical trial.

The second concern involved inadvertent dosing error, e.g. dosing with less than four hours of bedtime remaining. To assist patients in avoiding inadvertent dosing with less than 4 hours of remaining bedtime, management is evaluating and will propose to FDA modified use instructions and patient tools intended to help patients adhere to instructions to take Intermezzo only when 4 or more hours of bedtime remain. In addition, reinforcing messages are included throughout the product labeling to impress upon patients the importance of adhering to the 4 hour time window. These messages will be found in the Package Insert and the Medication Guide, and on each unit dose pouch, the patient tools, and a separate printed "Patient Instructions for Use", which is a user friendly insert that will be included in each box of 30 tablets.

Below is a depiction of the new prototype packaging for Intermezzo.



Our Conclusion: The new prototype packing demonstrations significant effort by the company to address the above FDA concerns. We would be very surprised to see any future issues with inadvertent double-dosing or instructions for use.

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. Despite this, epidemiology studies show significant off-label use of generic zolpidem used as a MOTN drug. Market research shows that physicians are even prescribing and recommending generic zolpidem and Lunesta for this potentially dangerous use. We view the approval of Intermezzo as an excellent opportunity for the FDA to offer physicians an approved and safer alternative.

Transcept has been conducting significant market research to prepare for the Intermezzo approval. In 2008, the company conducted market research with 45 psychiatrists and 133 primary care physicians, and reviewed with them over 890 of their insomnia patient records. This research indicated that when physicians encounter a patient whose primary insomnia complaint is middle of the night awakening with difficulty returning to sleep, 14% of these patients were instructed by their physician to utilize hypnotics in the middle of the night that have been approved only for bedtime use and that require 7 to 8 hours of time in bed before being active.

Beyond this initial market research, management is now sponsoring a scientifically rigorous epidemiology study to evaluate off-label use of sleep aids in the middle of the night. This study is being conducted by Dr. Ronald Kessler of the Harvard Medical School and is intended to quantify the magnitude of 7 to 8 hour hypnotic off-label drug usage in the middle of the night in a population of several thousand patients within a major health care system. The study is designed to provide important and quantitative insight into the clinical need for a drug like Intermezzo as evidenced by the current off-label use of existing hypnotics, none of which have been studied for safety or efficacy, nor packaged or approved for the as-needed treatment of middle of the night awakenings.

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.

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. 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.

Purdue has commercial rights to Intermezzo in the U.S. only, with the right to negotiate for commercial rights in Mexico and Canada. We think the European market is probably about similar in size in terms of prescriptions of the U.S. market; however, pricing in Europe is only 15% to 20% of U.S. pricing. Management has been in active discussions with potential European partners on Intermezzo. In fact, the company has reached the term sheet stage with several credible and interested parties. However, the company has concluded that the value of an Intermezzo partnership in Europe would be maximized after U.S. NDA approval. Accordingly, management has decided to place further discussions on hold until after the resubmission of the Intermezzo NDA.

Setrodon Phase II To Start Soon

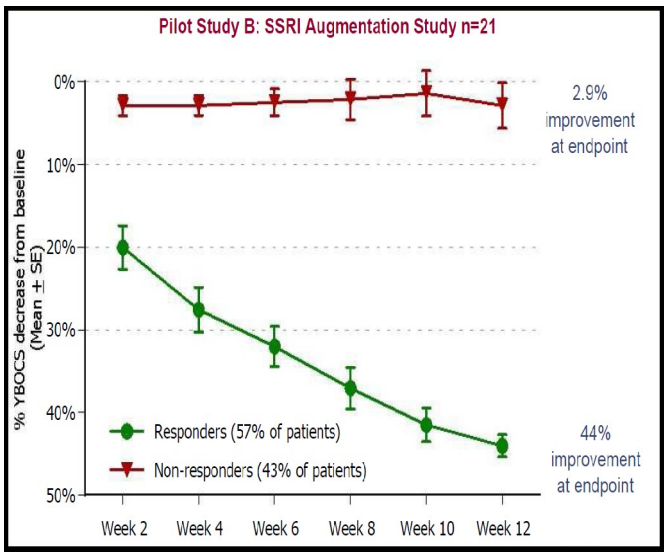
Transcept is currently preparing to start a phase II trial with Setrodon, an ultra low-dose ondansetron for potential use as an adjunctive therapy in adult patients with treatment-resistant obsessive compulsive disorder (TR-OCD). Ondansetron, a 5-HT_3 antagonist, was approved in January 1991 under the 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.

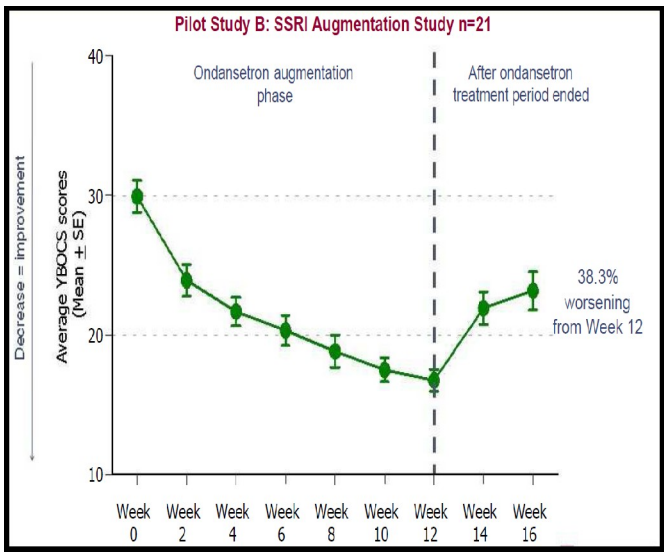
TR-OCD is an area where there are no FDA-approved treatment options for patients. OCD affects about 1% to 2% of the U.S. adult population. Only about half seek treatment. First-line therapy for OCD includes treatment with selective serotonin reuptake inhibitors (SSRI), including Prozac, Luvox, Paxil, 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 was been filed and accepted by the U.S. FDA in the second quarter 2010. Transcept will follow a 505(b)(2) pathway for Setrodon, relying on the substantial preclinical safety data on Zofran by GlaxoSmithKline. Typical doses of Zofran for CINV are 16mg to 24mg per day. The doses that Transcept plans to test in the double-blind, placebo-control phase II program will be 0.5mg BID and 0.75mg BID. The trial will seek to enroll up to 150 patients at 20 sites around the U.S. We estimate the program will take 9 months to enroll because management will institute rigorous entry criteria to confirm the subjects are indeed treatment-resistant. Thus, we are not expecting data until the second half of 2012. The program should cost around $10 million all-in.

Commercializing Setrodon presents an attractive opportunity to leverage the co-promotional agreement with Purdue pharma on Intermezzo to psychiatrist. We estimate there are roughly 1 million TR-OCD patients in the U.S. Even if only 50% seek treatment, the potential market opportunity to Transcept, assuming $5 per pill, is enormous:

- 225 million adult Americans…1.5% with OCD…
- 50% actively failing first-line SSRI…50% will seek physician Rx help…
- 25% market share for Setrodon…Setrodon costs $5 per day, taken daily…
- 225 million * 1.5% * 50% * 50% * 25% * 365 pills/year * $5 per pill ~ $400 million

By 2014, Transcept could be promoting both Intermezzo and Setrodon with a relatively small specialty field force directly into the psychiatry market. In our view, this is exactly the kind of leverage small biotech companies would love to take advantage of. It presents management with an opportunity to further expand the psychiatry pipeline in 2013 or beyond.

Stock Undervalued

We are maintaining our positive rating on Transcept Pharma. The stock is now trading with a market capitalization of $122 million. Over the past two months investors are clearly becoming more comfortable with the NDA resubmission and the approvability of Intermezzo. The stock is up 50% from the lows in early November 2010 since the company has completed the driving study in October 2010.

Cash on the balance sheet stood at $74 million at the end of September 2010. The company should still hold cash over $70 million when they report full year 2010 results. With the potential for an additional $16 million coming from Purdue in the third quarter 2011, Transcept's financial position remains very strong.

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 $8 million less the cash balance. Once Intermezzo is approved in about seven months, we would expect a similar rapid revaluation to significantly higher levels. The future successful development of Setrodon for treatment resistant obsessive compulsive disorder (TR-OCD) represents further upside to the story.

PROJECTED FINANCIALS

Transcept Pharmaceuticals, Inc.
Income Statement

	2008 A	2009 A	Q1 A	Q2 A	Q3 A	Q4 E	2010 E	2011 E	2012 E	2013 E
Intermezzo (US Sales)	$0	$0	$0	$0	$0	$0	$0	$26.0	$72.0	$120.0
Intermezzo (Ex-US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Intermezzo Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$6.1**	**$16.9**	**$28.2**
YOY Growth	-	-	-	-	-	-	-	-	*176.9%*	*66.7%*
Collaborations / Milestones	**$0**	**$5.2**	**$3.1**	**$3.1**	**$3.1**	**$3.1**	**$12.5**	**$27.3**	**$20.0**	**$20.0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Setrodon	**$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**	**$34.6**	**$36.9**	**$48.2**
YOY Growth	-	-	-	-	-	-	*140.0%*	*176.9%*	*6.7%*	*30.6%*
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	$2.8	$3.0	$3.2	$11.6	$12.8	$20.5	$23.5
% SG&A	-	*308.0%*	*83.3%*	*88.6%*	*95.5%*	*102.4%*	*92.5%*	*37.0%*	*55.5%*	*48.8%*
R&D	$10.4	$9.0	$2.4	$2.4	$2.9	$2.5	$10.2	$10.1	$10.0	$10.0
% R&D	-	*172.9%*	*75.5%*	*77.0%*	*92.3%*	*80.0%*	*81.2%*	*29.2%*	*27.1%*	*20.7%*
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)	($2.7)	($2.6)	($9.2)	$11.7	$6.4	$14.7
Operating Margin	-	-	-	-	-	-	-	*33.8%*	*17.4%*	*30.5%*
Interest & Other Net	$0.3	$0.3	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	($0.1)	$0.4	$0.5
Pre-Tax Income	($20.0)	($21.8)	($1.8)	($2.1)	($2.8)	($2.6)	($9.3)	$11.6	$6.8	$15.2
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	$0	$1.0	$4.6
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*15.0%*	*30.0%*
Net Income	($20.0)	($21.8)	($1.8)	($2.1)	($2.8)	($2.6)	($9.3)	$11.6	$5.8	$10.6
YOY Growth	-	-	-	-	-	-	-	-	*-50.2%*	*83.5%*
Net Margin	-	-	-	-	-	-	-	*33.6%*	*15.7%*	*22.1%*
Reported EPS	**($7.03)**	**($1.79)**	**($0.14)**	**($0.15)**	**($0.21)**	**($0.19)**	**($0.69)**	**$0.85**	**$0.41**	**$0.71**
YOY Growth	-	-	-	-	-	-	-	-	*-51.5%*	*71.3%*
Shares Outstanding	2.8	12.2	13.4	13.4	13.4	13.5	13.4	13.6	14.0	15.0

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

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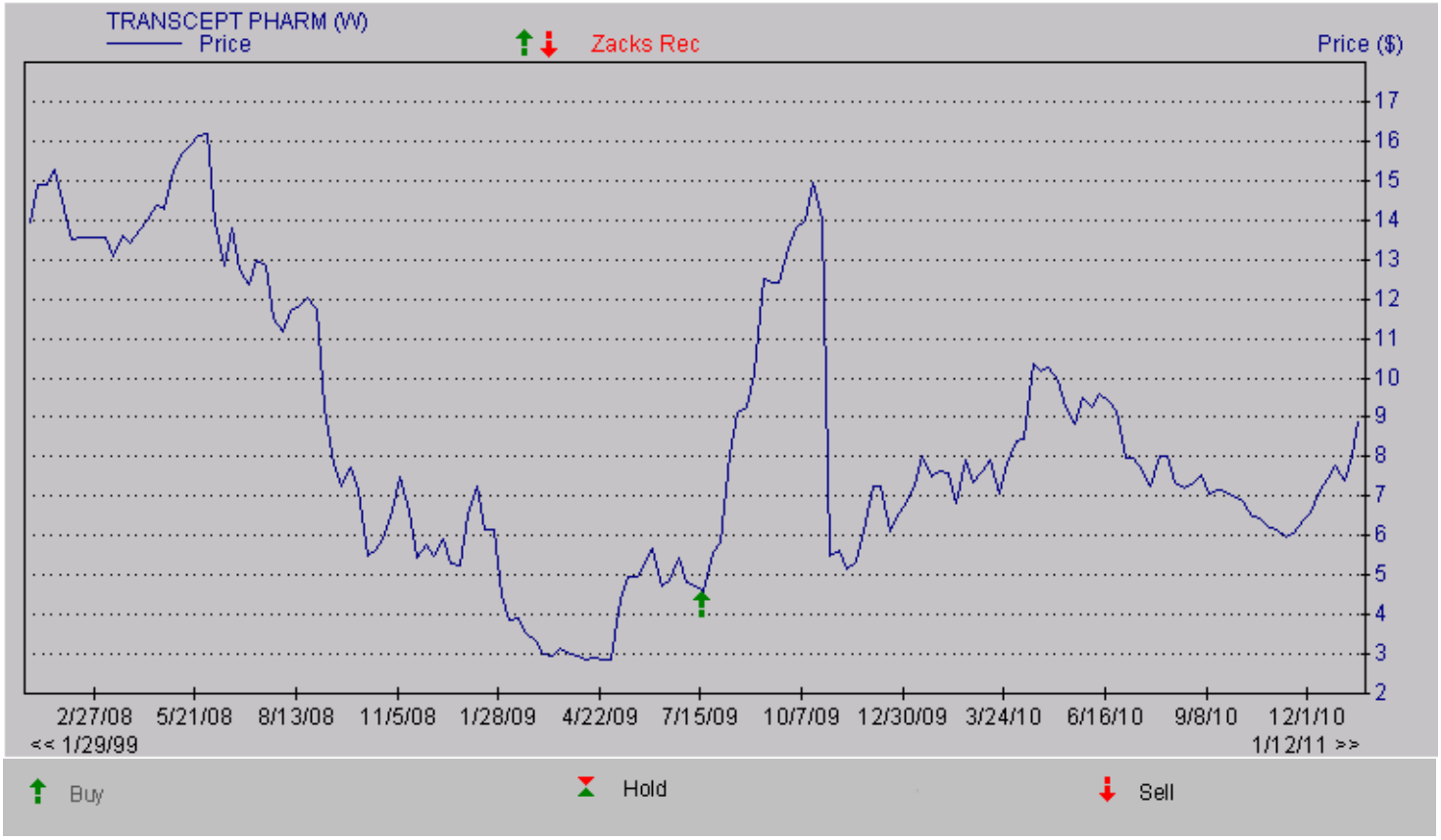
HISTORICAL ZACKS RECOMMENDATIONS



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