Zacks Small-Cap Research

November 11, 2011
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Transcept Pharmaceuticals, Inc. (TSPT-NASDAQ)

TSPT: Intermezzo PDUFA – November 27th.

UPDATE

The Intermezzo NDA is back under review and the U.S. FDA is set to rule on November 27, 2011. It's been a wild ride for Transcept investors over the past few months. Key questions remain on whether or not the FDA will approve the drug. Given the quick turnaround following the last CRL, the face-to-face meeting with the FDA and the Class-1 response, we would be very surprised to see another rejection. However, we've been wrong on Intermezzo in the past. We predicted approval in July 2011 before the second CRL.

We are going into the PDUFA with a Neutral rating and $8 target. We will re-evaluate following the FDA's decision.

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	07/12/2011
Current Price (11/11/11)	$7.70
Target Price	**$8.00**

SUMMARY DATA

52-Week High	**$11.73**
52-Week Low	**$2.63**
One-Year Return (%)	**27.42**
Beta	**1.91**
Average Daily Volume (sh)	**404,130**
Shares Outstanding (mil)	**14**
Market Capitalization ($mil)	**$105**
Short Interest Ratio (days)	**1.02**
Institutional Ownership (%)	**29**
Insider Ownership (%)	**43**
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**

Risk Level	**Average,**
Type of Stock	**Small-Value**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	3.1 A	3.1 A	3.1 A	3.1 A	12.5 A
2011	3.1 A	3.1 A	0.6 A	0.4 E	7.3 E
2012					12.3 E
2013					14.2 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.14 A	-$0.15 A	-$0.21 A	-$0.20 A	-$0.69 A
2011	-$0.14 A	-$0.17 A	-$0.37 A	-$0.33 E	-$1.01 E
2012					-$0.33 E
2013					-$0.19 E

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WHAT'S NEW

Third Quarter Financials

On November 10, 2011, Transcept reported financial results for the third quarter ended September 30, 2011. Transcept reported revenues in the quarter of $0.6 million, all of which includes recognition of the $25 million upfront payment from Purdue Pharma to licenses the U.S. rights to Intermezzo in August 2010. Net loss in the quarter totaled $5.0 million, or $0.37 per share. Transcept exited the third quarter with $54.1 million in cash and investments. We find this to be sufficient cash to fund operations for the foreseeable future, especially if Intermezzo gains approval in two weeks. There are two key IP transfers that will occur from Transcept to Purdue following approval. We model the first payment of $10 million (disclosed) to take place in early 2012. The second payment of $10 million (undisclosed) should take place later in 2012.

PDUFA Set For November 27th

In July 2011, Transcept Pharma received a complete response letter (CRL), the second such CRL, on Intermezzo. In the CRL, the *FDA noted that during its review of the Intermezzo NDA resubmission it became concerned that those patients with higher zolpidem blood levels from Intermezzo could be at risk of unacceptable next-day impairment, specifically with respect to driving ability. The FDA further hypothesized that such patients may belong to distinct and identifiable demographic groups*. As it turns out, the FDA was concerned specifically with lingering pharmacokinetic exposure in women – a zolpidem phenomenon that seems more significantly tied to gender than weight or body mass. This phenomenon has been evident in the literature dating back to the Ambien clinical program.

The FDA suggested to Transcept that *a possible path forward* would be to *further investigate whether body weight and demographic factors contribute to differentially elevated blood levels in the morning after dosing Intermezzo. Developing strategies to decrease next morning zolpidem levels and after mitigation strategies are implemented demonstrate that next morning blood levels do not present an unacceptable risk of next-day impairment, which based on FDA comments included the possibility of an additional driving study.*

Following these comments, most investors believed the drug was dead. However, submitted a briefing package to the FDA shortly after the CRL. Transcept suggested two key changes to the proposed label for Intermezzo.

- The first was to reduce the proposed dose in women to 1.75mg from 3.5mg. According to management, the decision to reduce the dose in non-elderly women from 3.5 milligrams to 1.75 milligrams was based on a reanalysis of bioavailability data that showed that women had blood levels that were approximately 40% higher than men based on measurements of Cmax and calculations of area under the curve (AUC). In addition, a further analysis of efficacy data from the Intermezzo phase 3 sleep lab study (n=80) demonstrated that 3.5 milligrams of Intermezzo in non-elderly men and 1.75 in non-elderly women produced similar response curves as measured by the number of patients asleep at time points between 5 and 30 minutes post dose. Transcept also conducted an out-patient study (n=300) during the phase 3 program as well.

- The second was to instruct that Intermezzo only be taken if patients have at least four hours of bedtime remaining and five hours before driving post dose. This decision was based on bioavailability analysis conducted by Transcept during the clinical program which showed minimum residual blood levels at 5 hours post dose.

On September 13, 2011, the FDA responded to the briefing package in a face-to-face meeting with Transcept management communicating that it *generally agreed with these Transcept proposals and indicated that if the NDA resubmission was adequately concise, the Agency might be able to consider this as a Class-1 resubmission* – which qualifies for a two month review.

Following this meeting with the FDA, Transcept re-filed its new drug application (NDA) on Intermezzo on September 27, 2011. The re-file was a combination of restatement of previous data and some re-analysis of previously generated data. None of the data was new. **The NDA re-file was only 11 pages long**.

The FDA quickly accepted the filing and established a new PDUFA (Class-1) action date of November 27, 2011. It seems like the FDA asked Transcept to keep it concise and simple, and Transcept obliged. We hope that does not come back to burn them on the 27th of November.

…Some Key Points To Consider…

1) During the driving study, which was about 50% women (n~40) conducted at the Maastricht University, management did not observe any meaningful difference between how men and women performed on the highway in terms of standard deviation of lateral position (SDLP). CEO Glenn Oclassen noted the data "sort of walked around randomly" and at the 4 hour post dose test (sleep time of 3 hours 15 minutes) the data did not show any clear signs on mean. At 3 hours post dose (sleep time of 2 hours 15 minutes) one female subject had to stop driving due to potential risk.

   - This should not be an issue for approval. With no statistically meaningful differences in SDLP at 4 hours post dose, the FDA should be ok with the new label suggesting 5 hours post dose. We think this essentially addresses the FDA's concern with respect to implementing mitigation strategies.

2) The FDA remains concerned that patients will miss-dose in the middle-of-the-night. Both CRLs stressed issues with miss-dosing leading to potentially dangerous zolpidem blood levels having an effect on driving ability.

   - This is essentially the key wildcard that remains for approval. Has Transcept adequately shown that Intermezzo is a drug that can be used safely in the middle of the night? From the previous CRL, Transcept altered the packing and increased the language on the outside of the box to help avert potential double-dosing and dosing too soon before waking up to drive. Transcept did not conduct a patient use study with the new labeling instructions. The FDA noted in the second CRL that a patient use study was no necessary.

3) Transcept did not conduct another driving study with women testing the 1.75 mg dose. Management is relying on blood level analysis alone to prove that the drug is safe at this new lower dose and at 5 hours post dose. In the previous CRL, the FDA opined that blood level analysis alone, along with things like DSST and comparisons to things like blood alcohol levels may not be sufficient to address its concerns.

   - Similar to the changes in SDLP, this remains the key area of concern going into PDUFA. The FDA seems to have clearly steered Transcept toward a quick and simple response, as evidenced by the correspondence and the Class-1 review. Management could have done another driving study. The delay would have been around 1 year to re-file. That being said, if the FDA is telling you do not bother, then you have to trust them – we hope. What concerns us is that is seems like subjects react differently to Intermezzo. As a mean, there were no statistically significant differences with SDLP at 4 hours post dose, but on an individual basis blood levels and driving ability were varied. This seems like a loose-end. The FDA does not usually allow loose ends. What management did tell us is that Intermezzo blood levels at 4-5 hours post dose look similar to Ambien and Ambien-CR blood levels at 8-9 hours post dose.

What Happens Post Approval

Purdue has 10 business days to opt-into the commercialization right. We would be surprised to see them walk away from the drug if approved. We remind investors that Transcept will receive no approval milestone from Purdue, but is eligible for a $10 million milestone on the transfer of the first patent listed in the FDA's Orange Book to Purdue. There is an additional IP transfer milestone for the listing of the second patent in the FDA's Orange Book. The amount has not been disclosed, but we suspect it is a similar $10 million. There are an additional $70 million in sales related milestones eligible post-launch, along with an undisclosed (mid-teens to low-20's) royalty on sales, along with the potential for an additional double-digit royalty on co-promotion from Transcept eligible one year post the Purdue launch.

Following approval, questions remain on whether or not the new label proposal and instructions for use are restrictive and have reduced the sales potential for the drug. We currently see peak sales for the drug at $254 million in 2020. We have published our market assumptions in the back of this report. In the meantime, Transcept is sitting with $54.1 million in cash and investments as of September 30, 2011. This provides enough cash to fund operations and allow management to develop TO-2061 for TR-OCD or in-license a new late-stage CNS drug. Our DCF model shows fair-value is just over $12 per share when including the current cash balance, the expected royalties from Intermezzo, and a heavily discounted future around TO-2061.

PROJECTED FINANCIALS

Transcept Pharmaceuticals, Inc.
Income Statement

	2009 A	2010 A	Q1 A	Q2 A	Q3 A	Q4 E	2011 E	2012 E	2013 E	2014 E
Intermezzo (US Sales)	$0	$0	$0	$0	$0	$0	$0	$11.7	$66.2	$131.4
Intermezzo (Ex-US Sales)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Intermezzo Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$2.3**	**$14.2**	**$29.6**
YOY Growth	-	-	-	-	-	-	-	-	-	-
Collaborations / Milestones	**$5.2**	**$12.5**	**$3.1**	**$3.1**	**$0.6**	**$0.4**	**$7.3**	**$10.0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-	-
TO-2061	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-					-	-	-	-
Total Revenues	**$5.2**	**$12.5**	**$3.1**	**$3.1**	**$0.6**	**$0.4**	**$7.3**	**$12.3**	**$14.2**	**$29.6**
YOY Growth	-	*140.0%*	-	-	-	-	*-41.6%*	*68.2%*	*95.2%*	*140.9%*
Cost of Goods Sold	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	-	-	-	-	-	-	-	-	-	-
SG&A	$16.0	$11.0	$2.5	$2.6	$2.9	$2.5	$10.5	$8.5	$9.0	$9.5
% SG&A	*308.0%*	*88.3%*	*81.4%*	*82.6%*	*467.0%*	*595.2%*	*144.6%*	*69.3%*	*63.2%*	*32.1%*
R&D	$9.0	$10.7	$2.5	$2.8	$2.7	$2.4	$10.3	$10.0	$10.0	$10.0
% R&D	*172.9%*	*85.5%*	*79.7%*	*88.4%*	*426.9%*	*571.4%*	*141.5%*	*81.5%*	*70.2%*	*33.8%*
Merger & Other Costs	$2.2	$0	$0	$0	$0	$0	$0	$0	$0	$0
Operating Income	($22.1)	($9.2)	($1.9)	($2.2)	($5.0)	($4.5)	($13.6)	($6.2)	($4.8)	$10.1
Operating Margin	-	-	-	-	-	-	*-186.0%*	*-50.7%*	*-33.4%*	*34.0%*
Interest & Other Net	$0.3	($0.1)	($0.0)	($0.0)	($0.0)	($0.0)	($0.1)	$0.4	$0.5	$0.5
Pre-Tax Income	($21.8)	($9.3)	($1.9)	($2.2)	($5.0)	($4.5)	($13.7)	($5.8)	($4.3)	$10.6
Taxes / Other	$0	$0	$0	$0	$0	$0	$0	($0.9)	($1.3)	$3.2
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*15.0%*	*30.0%*	*30.0%*
Net Income	($21.8)	($9.3)	($1.9)	($2.2)	($5.0)	($4.5)	($13.7)	($5.0)	($3.0)	$7.4
YOY Growth	-	-	-	-	-	-	-	*-63.8%*	*-78.2%*	*-249.3%*
Net Margin	-	-	-	-	-	-	*-187.6%*	*-40.4%*	*-20.9%*	*25.0%*
Reported EPS	**($1.79)**	**($0.69)**	**($0.14)**	**($0.17)**	**($0.37)**	**($0.33)**	**($1.01)**	**($0.33)**	**($0.19)**	**$0.43**
YOY Growth	-	-	-	-	-	-	-	*-67.4%*	*-81.6%*	*-231.7%*
Shares Outstanding	12.2	13.4	13.5	13.5	13.5	13.6	13.5	15.0	16.0	17.0

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

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Transcept Pharmaceuticals, Inc.
DCF Valuation - Revenue Model (Part-1)

Transcept, Inc.	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	
Adults in the U.S. (Millions)	235	237	240	242	245	247	249	252	254	257	260	
Percent with MOTN-Awaken	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	*35%*	
Percent with MOTN-Insomnia	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	*45%*	
Percent w/o Onset Issues	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	*60%*	
Target Market (Millions)	22.2	22.4	22.7	22.9	23.1	23.3	23.6	23.8	24.0	24.3	24.5	
Percent Seeking Rx Help	*14%*	*15%*	*16%*	*16%*	*17%*	*17%*	*17%*	*18%*	*18%*	*18%*	*18%*	
Active Users (Millions)	3.1	3.4	3.6	3.7	3.8	3.9	4.1	4.2	4.3	4.4	4.5	
Market Share (@Purdue)	*1.0%*	*3.5%*	*5.5%*	*6.0%*	*6.5%*	*7.0%*	*7.0%*	*7.3%*	*7.5%*	*7.0%*	*6.5%*	
Co-Promotion (@Transcept)	*0%*	*0%*	*0.3%*	*0.6%*	*0.9%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	*1.0%*	
Doses / Year	*125*	*125*	*125*	*125*	*125*	*125*	*125*	*125*	*125*	*125*	*125*	
Cost per Pill (Net)	*$3.00*	*$4.50*	*$5.00*	*$5.10*	*$5.20*	*$5.31*	*$5.36*	*$5.47*	*$5.58*	*$5.63*	*$5.69*	
Intermezzo Sales at Purdue	$11.7	$66.2	$131.4	$156.9	$184.6	$209.3	$217.3	$236.3	$253.6	$247.6	$240.7	
Royalty on Intermezzo	$1.7	$9.9	$23.7	$29.0	$34.9	$39.6	$41.1	$44.6	$47.8	$46.9	$45.8	*X-2025*
Milestones from Purdue	$10.0	$10.0	$0	$0	$10.0	$0	$0	$10.0	$0	$0	$0	
Sales of TO-2061	$0	$0	$0	$0	$9.2	$20.2	$31.8	$44.6	$58.6	$64.0	$69.8	*X-2026*
TSPT Revenues (in Millions)	**$11.7**	**$19.9**	**$23.7**	**$29.0**	**$54.0**	**$59.8**	**$73.0**	**$99.2**	**$106.3**	**$110.8**	**$115.6**	

Transcept Pharmaceuticals, Inc.
DCF Valuation – Cash Flow (Part-2)

Transcept, Inc.	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	
Royalty on Intermezzo	$1.7	$9.9	$23.7	$29.0	$34.9	$39.6	$41.1	$44.6	$47.8	$46.9	$45.8	*X-2025*
Milestones from Purdue	$10.0	$10.0	$0	$0	$10.0	$0	$0	$10.0	$0	$0	$0	
Sales of TO-2061	$0	$0	$0	$0	$9.2	$20.2	$31.8	$44.6	$58.6	$64.0	$69.8	*X-2026*
TSPT Revenues (in Millions)	**$11.7**	**$19.9**	**$23.7**	**$29.0**	**$54.0**	**$59.8**	**$73.0**	**$99.2**	**$106.3**	**$110.8**	**$115.6**	
CoGS	*$0*	*$0*	*$0*	*$0.0*	*$0.9*	*$2.0*	*$3.2*	*$4.5*	*$5.9*	*$6.4*	*$7.0*	
R&D	*$10.0*	*$12.5*	*$15.0*	*$10.0*	*$10.0*	*$10.0*	*$10.0*	*$9.9*	*$10.6*	*$11.1*	*$11.6*	
SG&A	*$8.5*	*$9.0*	*$12.0*	*$13.0*	*$16.9*	*$19.0*	*$21.2*	*$23.5*	*$25.9*	*$26.4*	*$27.0*	
Other Expenses	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	
EBITDA	($6.8)	($1.6)	($3.3)	$6.0	$26.2	$28.8	$38.6	$61.4	$64.0	$67.0	$70.1	
Depreciation and amortization	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	*$0.5*	
EBIT	**($7.3)**	**($2.1)**	**($3.8)**	**$5.5**	**$25.7**	**$28.3**	**$38.1**	**$60.9**	**$63.5**	**$66.5**	**$69.6**	
EBITDA margin	-	-	*-16.0%*	*19.0%*	*47.6%*	*47.3%*	*52.2%*	*61.3%*	*59.7%*	*60.0%*	*60.2%*	
Cash Taxes	$0	$0	$0	$0	($1.3)	($4.2)	($12.2)	($19.5)	($20.3)	($21.3)	($22.3)	
Tax Rate	-	-	-	*0%*	*5.0%*	*15.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*	*32.0%*	
Balance Sheet												
Capital Expenditures	$0.5	$2.0	$2.5	$4.0	$2.5	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	
Working Capital	($1.0)	($1.0)	($1.0)	($0.5)	($0.5)	$0.0	$0.5	$1.0	$1.0	$1.0	$1.0	
Other Cash Adjustments	($1.0)	($1.2)	($1.4)	($1.6)	($1.8)	($2.0)	($2.2)	($2.4)	($2.6)	($2.8)	($3.0)	
Capital Adjustments	**($1.5)**	**($0.2)**	**$0.1**	**$1.9**	**$0.2**	**($1.0)**	**($0.7)**	**($0.4)**	**($0.6)**	**($0.8)**	**($1.0)**	
Net Margin	*-61.7%*	*-10.4%*	*-16.0%*	*19.0%*	*45.2%*	*40.2%*	*35.5%*	*41.7%*	*40.6%*	*40.8%*	*40.9%*	
Discounted Cash Flow												
Net Income	($7.3)	($2.1)	($3.8)	$5.5	$24.4	$24.0	$25.9	$41.4	$43.2	$45.2	$47.3	
Depreciation and amortization	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	$0.5	
Net Cash Adjustments	$1.5	$0.2	($0.1)	($1.9)	($0.2)	$1.0	$0.7	$0.4	$0.6	$0.8	$1.0	
Post-Tax Operating Cash Flow	**($5.3)**	**($1.4)**	**($3.4)**	**$4.1**	**$24.7**	**$25.5**	**$27.1**	**$42.3**	**$44.3**	**$46.5**	**$48.8**	
Dividends	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	
Free Cash Flow	**($5.3)**	**($1.4)**	**($3.4)**	**$4.1**	**$24.7**	**$25.5**	**$27.1**	**$42.3**	**$44.3**	**$46.5**	**$48.8**	

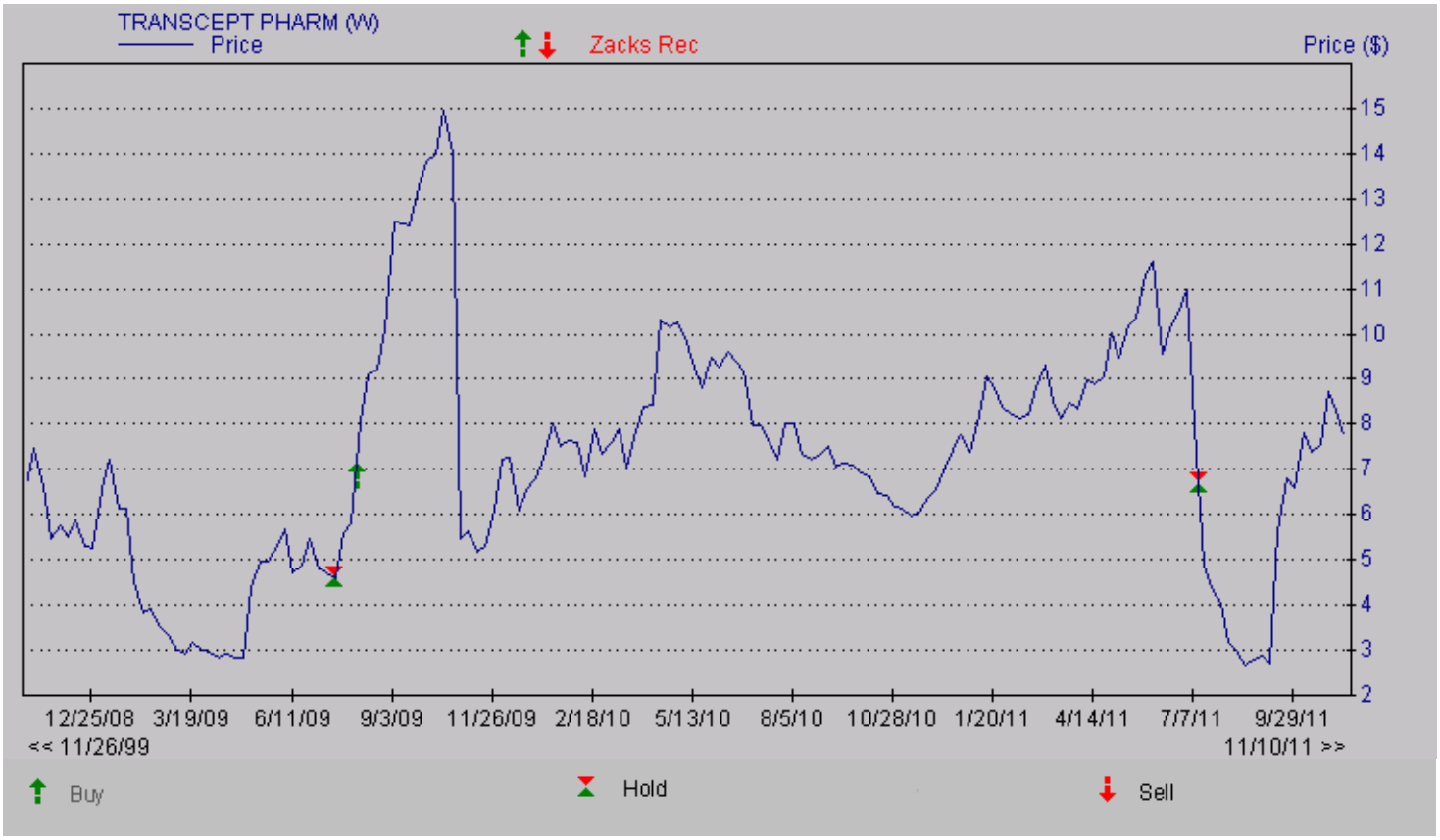
Assumptions	
Beta:	1.5
Equity Risk Premium:	8%
Risk Free Rate:	3%
Firm Risk Premium:	50%
Discount Rate:	**15.0%**

Valuation	
10-Year Model:	$76
Terminal Growth:	3%
Terminal Value:	$90
Net Cash - LT Debt:	$50
Firm Value:	**$216**

Price Target	
Basic Outstanding:	13.5
Options / Warrants:	3.5
Dilution:	1.0
Fully Diluted:	18.0
Target Price:	**$11.97**

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

HISTORICAL ZACKS RECOMMENDATIONS



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