Zacks Equity Research

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# Transcept Pharmaceuticals, Inc. (TSPT-NASDAQ)

***TSPT: Driving Study Shows Intermezzo Has Little To No Next-Day Residual Effect. Transcept To Re-File The NDA In The Q1-2011.***

| | |
|---|---|
| **Current Recommendation** | **Outperform** |
| Prior Recommendation | Neutral |
| Date of Last Change | 08/10/2009 |
| Current Price (10/19/10) | $6.75 |
| **Target Price** | **$12.00** |

## UPDATE

This morning Transcept released a preliminary analysis of the recently completed Intermezzo highway driving study. The data show little to no next-day residual effect on highway driving for patients four hours after taking Intermezzo 3.5mg. We believe this data, along with product labeling and packaging changes and improved instructions for use, have now addressed all the key issues raised in the FDA's complete response letter from last October 2009. Management is continuing to analyze the data from the driving study, but we anticipate that the company will be in position to re-file for approval during the first quarter 2011. That puts an action date in July or August 2011. With over $74 million in cash still on the books and a market value of only $92 million, Transcept offers enormous upside once Intermezzo is finally approved by the FDA.

## SUMMARY DATA

| | |
|---|---|
| **52-Week High** | **$15.12** |
| **52-Week Low** | **$4.64** |
| **One-Year Return (%)** | **-56.28** |
| **Beta** | **2.17** |
| **Average Daily Volume (sh)** | **40,048** |
| **Shares Outstanding (mil)** | **13** |
| **Market Capitalization ($mil)** | **$89** |
| **Short Interest Ratio (days)** | **18.72** |
| **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** | **68 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 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 A | -$0.18 E | -$0.19 E | -$0.67 E |
| 2011 | | | | | $0.73 E |
| 2012 | | | | | $0.54 E |

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

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## WHAT'S NEW

***Driving Study Backgrounder…***

This morning, 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.

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 of 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.

*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.*

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 data is necessary. And we fully expect that management will present and/or publish the data after a full analysis in 2011. However, based on these preliminary results, we believe that management can claim Intermezzo provides no meaningful residual effect when dosed correctly in the middle-of-the-night when a patient can devote a minimum of 4 hours to sleep. 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.

With the successful completion of the driving study, we believe Transcept has taken a significant effort to address the concerns raised by the FDA with regard to the potential for inadvertent dosing with less than four hours remaining in bed or re-dosing twice in one night.

***Transcept to Re-File In Q1-2011***

Management will now spend the next few months preparing the NDA for resubmission. We expect that the company will be in position to re-file for approval during the first quarter 2011. The FDA will review as a class-II resubmission, meaning potential FDA action will coming in July or August 2011. We estimate the approval, IP transfer, and launch milestone will be in the area of $14 to $16 million. Once launched, Transcept will receive a double-digit royalty up to mid 20% on net sales at U.S. partner, Purdue Pharmaceuticals. 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.

## 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.

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.

***Stock Undervalued…***

We are maintaining our positive rating on Transcept Pharma. The stock is now trading with a market capitalization of only $92 million, just $18 million above the cash on the balance sheet of $74 million at the end of September 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 $18 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 treatment resistant obsessive compulsive disorder (TR-OCD) represents further upside to the story.

## PROJECTED FINANCIALS

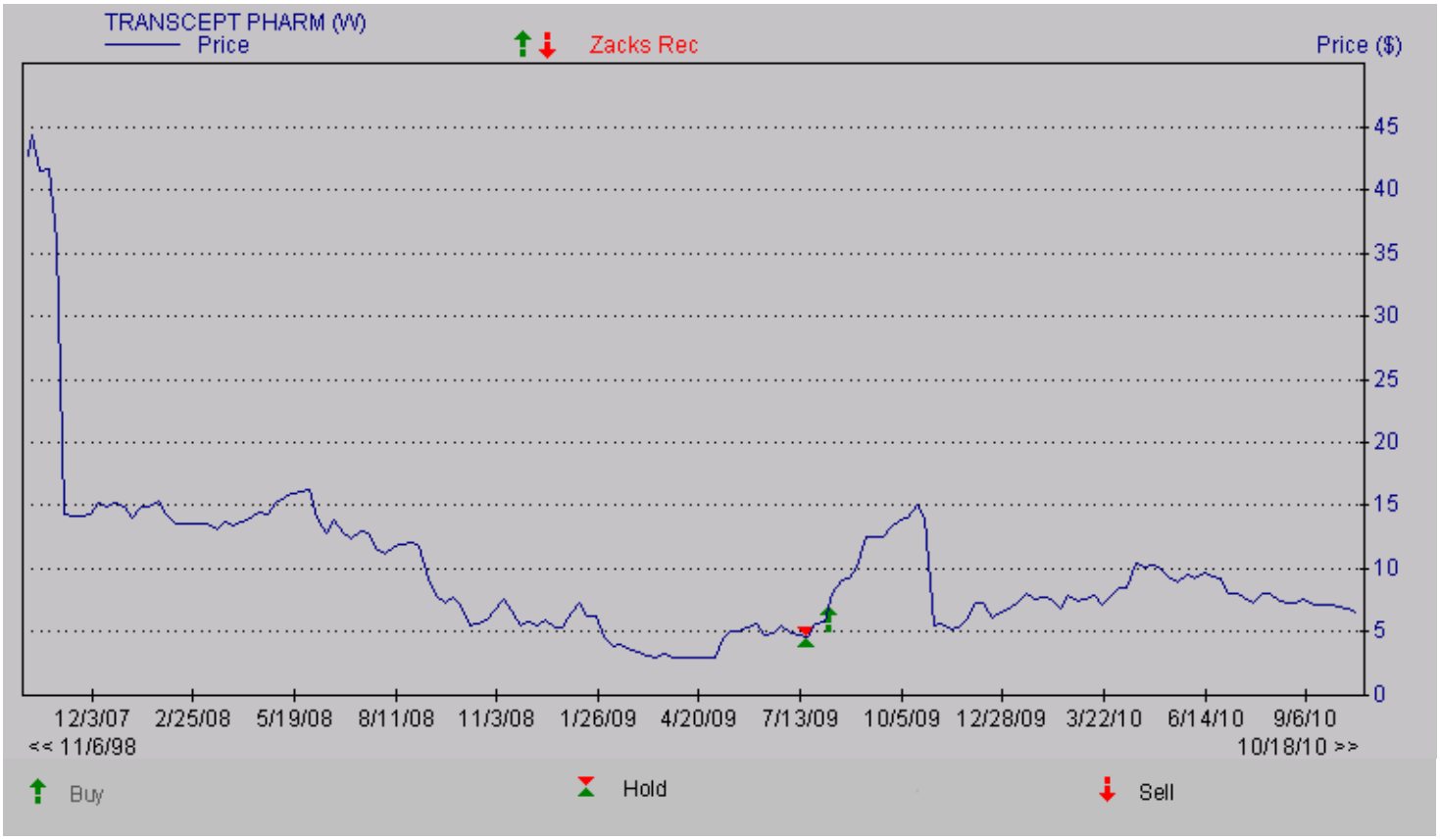
**Transcept Pharmaceuticals, Inc.**
Income Statement

| | 2008 A | 2009 A | Q1 A | Q2 A | Q3 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 | $2.8 | $3.0 | $3.3 | $11.7 | $13.5 | $20.5 | $23.5 |
| *% SG&A* | - | *308.0%* | *83.3%* | *88.6%* | *96.0%* | *105.6%* | *93.4%* | *40.4%* | *52.2%* | *42.6%* |
| R&D | $10.4 | $9.0 | $2.4 | $2.4 | $2.6 | $2.4 | $9.8 | $10.0 | $10.0 | $10.0 |
| *% R&D* | - | *172.9%* | *75.5%* | *77.0%* | *83.2%* | *76.8%* | *78.1%* | *29.9%* | *25.5%* | *18.1%* |
| 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) | ($8.9) | $9.9 | $8.8 | $21.7 |
| *Operating Margin* | - | - | - | - | - | - | - | *29.6%* | *22.3%* | *39.3%* |
| 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 | $9.2 | $22.2 |
| Taxes / Other | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $0 | $1.4 | $6.7 |
| *Tax Rate* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *0%* | *15.0%* | *30.0%* |
| Net Income | ($20.0) | ($21.8) | ($1.8) | ($2.1) | ($2.5) | ($2.6) | ($9.0) | $10.2 | $7.8 | $15.5 |
| *YOY Growth* | - | - | - | - | - | - | - | - | *-23.6%* | *99.1%* |
| *Net Margin* | - | - | - | - | - | - | - | *30.5%* | *19.8%* | *28.1%* |
| **Reported EPS** | **($7.03)** | **($1.79)** | **($0.14)** | **($0.15)** | **($0.18)** | **($0.19)** | **($0.67)** | **$0.73** | **$0.54** | **$1.03** |
| *YOY Growth* | - | - | - | - | - | - | - | - | *-26.2%* | *92.5%* |
| Shares Outstanding | 2.8 | 12.2 | 13.4 | 13.4 | 13.5 | 13.5 | 13.4 | 14.0 | 14.5 | 15.0 |

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

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## HISTORICAL ZACKS RECOMMENDATIONS




## DISCLOSURES

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