Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-OTC)

TTNP: Betting On A Glass-Half-Full Scenario…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (05/16/12)	$0.65
Target Price	**$2.50**

UPDATE

Titan is wrapping up the necessary CMC and EVA characterization work to submit to the U.S. FDA, along with the NDA for approval, in October 2012. The opportunity exists for Titan to seek a priority review on Probuphine. We see Probuphine as a potential $300 million product in the U.S., with an opportunity to increase this peak level by expanding sales to outside the U.S. at a later date.

In the meantime, a partnership remains the key value drive for the shares. We remain optimistic on the story and see the shares as meaningfully under-valued at today's price. Our target is $2.50 based on our DCF model.

SUMMARY DATA

52-Week High	**$1.85**
52-Week Low	**$0.65**
One-Year Return (%)	**-64.86**
Beta	**9.76**
Average Daily Volume (sh)	**94,418**
Shares Outstanding (mil)	**66**
Market Capitalization ($mil)	**$43**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**1**
Insider Ownership (%)	**15**
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 2012 Estimate	**N/A**
P/E using 2013 Estimate	**N/A**

Risk Level	**Above Average**
Type of Stock	**Small-Growth**
Industry	**Med-Biomed/Gene**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.9 A	0.7 A	1.0 A	1.4 A	4.1 A
2012	1.3 A	1.4 A	1.3 E	16.3 E	20.2 E
2013					30.0 E
2014					17.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.08 A	-$0.12 A	-$0.01 A	-$0.05 A	-$0.26 A
2012	-$0.09 A	-$0.03 A	-$0.04 E	$0.19 E	$0.08 E
2013					$0.19 E
2014					$0.05 E

Zacks Projected EPS Growth Rate - Next 4 Years % **N/A**

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WHAT'S NEW

Financial Situation

On August 10, 2012, Titan Pharmaceuticals reported financial results for the second quarter ended June 30, 2012. Total revenues in the quarter were $1.4 million, driven by royalties on U.S. sales of Fanapt at Novartis AG. We remind investors that in November 2011, Titan entered into an agreement with Deerfield pursuant to which Titan owns a substantial portion of the remaining royalty payments on U.S. sales of Fanapt in exchange for $5 million in cash and $10 million in debt forgiveness on a previous loan facility with Deerfield. Royalties for the second quarter of $1.4 million were essentially in-line with our model.

Net loss for the second quarter 2012 was $1.7 million, or 3 cents per share. This was slightly better than our expectations on lower-than-expected SG&A expense. Cash burn for the quarter totaled $3.1 million. Operating and investing burn for the first six months of the year totaled $6.1 million. Titan exited the second quarter ended June 30, 2012 with $4.1 million in cash and investments. Titan believes their existing cash balance is sufficient to fund operations into October 2012.

In April 2012, Titan raised $5.5 million through a registered direct offering of 6.517 million shares of common stock at $0.85 per share. Included in the deal were an equal amount of Series-A and Series-B warrants. The Series-A warrants have an exercise price of $1.15 per share and are exercisable starting in October 2012 for a period of six years. The Series-B warrants went active at closing of the deal at a price of $0.85 per share and will expire in October 2012. Based on the current stock price, we expect these Series-B warrants will expire worthless. Net proceeds from the deal were approximately $5.2 million.

NDA Planned For October

Titan believes it is on track to file the New Drug Application (NDA) with the U.S. FDA in October 2012. This is approximately a one-month delay from the last update as of May 2012. Management is currently completing its analytical testing of Probuphine to provide additional Chemistry, Manufacturing and Control (CMC) data requested by the FDA along with its preparation of the integrated clinical data, summary reports and electronic document preparation. As a reminder, the FDA requested that Titan provide a full characterization of the ethylene-vinyl acetate (EVA) rod that is inserted under the skin containing the buprenorphine product. Specifically, the FDA would like to know about the potential for impurities in the EVA rod and the potential for leakage at concentrations that are above safe plasma levels. Titan is providing this characterization to the FDA and believes the EVA rod presents no safety risk to patients.

According to management, the manufacturing facility expansion and qualification for commercial scale production of Probuphine is in process and the first production of the qualification batches will be completed in late August 2012. We remind investors that the manufacturing for Probuphine will take place at a cGMP contract manufacturer, DPT Labs, located in San Antonio, TX. Demonstration of commercial scale production capability is a requirement prior to submission of the NDA. Unfortunately, finalizing production at the new facility took longer than expected and now Titan is in a precarious financial situation.

Titan expects to petition the U.S. FDA under the small business entity exemption, allowing filing of the NDA without the customary $1.8 million PDUFA expense. We believe that Titan qualifies for this exemption, and management sounded pretty confident on the second quarter call that they will get it, but caution investors that management's guidance to file the NDA in October does not include this fee. The NDA will be via the FDA's 505(b)(2) pathway for a reformulation of previously approved buprenorphine active molecule.

During the companies pre-NDA meeting the FDA has provided Titan with guidance on what would be necessary to submit the application requesting a Priority Review. The FDA grants a Priority Review for products believed to address unmet medical needs. The designation shortens the average amount of time from completed application until approval decision from 10 months to 6 months as defined under PDUFA. If the application is filed in October 2012, Priority Review puts the FDA action date in April 2013. Regular review puts FDA action in August 2013. We are cautious on modeling Priority Review because of the inclusion of a Risk Evaluation and Mitigation Strategy (REMS) within the NDA. The FDA has granted Priority Review to drugs that require a REMS in the past (ipilimumab comes to mind), but we do not model approval of Probuphine until August 2013. We note that ipilimumab, despite being granted Priority Review, still took 9 months to approve.

…Time To Partner…

Management's goal is to secure one or more commercialization partnerships prior to running out of cash in October 2012. It is clear that securing a commercialization partner is imperative unless shareholders want to see another dilutive offering. Nevertheless, management notes it is "evaluating options" for bridge financing if need be. Management has noted being in discussion with a handful of potential licensing partners on Probuphine. Talks have progressed to the term sheet stage and on the second quarter call management reported making great progress with the "front-runner". Obviously Titan would like to get a deal done sooner rather than later, and we think potential partners have interest in providing feedback on the NDA before Titan files. Therefore, we are going out on a limb and modeling a partnership in October 2012 just prior to the NDA filing.

We think Probuphine, with potential peak sales of $300 million, could fetch as much as $15 to 20 million upfront, with another similar amount for approval, along with a tiered royalty that pays Titan roughly 20% on U.S. sales. We think there is significant demand for a product like Probuphine. We note that the phase 3 PRO-806 trial enrolled four months ahead of schedule. Over 500,000 patients are prescribed some formulation of Suboxone yearly. Reckitt Benckiser (RB) only actively promotes the film version. We estimate that is nearly 50% of the market. The transition from oral Suboxone to the film has been success for RB.

Titan recently presented data from the confirmatory phase 3 program at the American Society of Addiction Medicine (ASAM) meeting in April 2012. Management noted the presentation was well attended and that clinician interest in the data was high, including many physicians asking when the product would be available and how they can learn more about doing the implantation procedure. The company plans to be active at several medical meetings in the next few months to build awareness around the product.

We think Titan and its partner will find success converting the remaining 50% of the oral Suboxone prescribers, or even a good percent of the film market, over to the six-month implant. To achieve our peak sales forecast of $300+ million, our financial model assumes only 10% market share (at $2,500 per implant). There are over 1.2 million patients seeking treatment for opioid addiction in the U.S. alone. It's a fairly sizable opportunity for a commercialization partner.

Stock Looks Under-Valued

We see Titan shares as meaningfully under-valued today. Our scenario for Probuphine assumes a new drug application (NDA) in October 2012, and approval in August2013. We expect a U.S. deal around the time of the NDA filing, which should bring upfront cash in the area of $15 to $20 million, a similar approval milestone in mid-2013, backend milestone totaling $100 million, and a ~20% royalty on sales.

Under this scenario, we see the net present value (NPV) of Titan's cash from a deal, risk-adjusted backend milestones, and royalties on sales worth $200 million, or around $2.50 per diluted share. We've posted our DCF model below:

Titan Pharmaceuticals	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022
Royalty on Fanapt (8-10%)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YoY Growth	-	-	-	-	-	-	-	-	-	-	-
Royalty on Probuphine (22%)	$0	$5.2	$13.3	$23.7	$34.5	$42.3	$50.3	$58.7	$63.6	$61.1	$62.3
YoY Growth	-	-	*155%*	*79%*	*46%*	*22%*	*19%*	*17%*	*8%*	*-4%*	*2%*
Licensing & Milestones	$20.0	$20.0	$0	$0	$5.0	$0	$10.0	$0	$0	$0	$0
Revenues (in Millions)	**$20.0**	**$25.2**	**$13.3**	**$23.7**	**$39.5**	**$42.3**	**$60.3**	**$58.7**	**$63.6**	**$61.1**	**$62.3**
CoGS	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*
R&D	*$8.5*	*$5.0*	*$6.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*
SG&A	*$5.1*	*$6.0*	*$7.0*	*$7.0*	*$7.0*	*$7.0*	*$7.0*	*$7.0*	*$7.0*	*$7.0*	*$7.0*
Other Expenses	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*
EBITDA	$6.4	$14.2	$0.3	$11.7	$27.5	$30.3	$48.3	$46.7	$51.6	$49.1	$50.3
Depreciation and amortization	*$1.0*	*$1.0*	*$1.0*	*$1.0*	*$1.0*	*$1.0*	*$1.0*	*$1.0*	*$1.0*	*$1.0*	*$1.0*
EBIT	**$5.4**	**$13.2**	**($0.7)**	**$10.7**	**$26.5**	**$29.3**	**$47.3**	**$45.7**	**$50.6**	**$48.1**	**$49.3**
EBITDA margin	*27.0%*	*52.4%*	*-5.4%*	*45.2%*	*67.1%*	*69.3%*	*78.4%*	*77.8%*	*79.6%*	*78.7%*	*79.1%*
Cash Taxes	$0	$0	$0	$0	$0	($4.4)	($14.2)	($13.7)	($15.2)	($14.4)	($14.8)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*15.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*
Balance Sheet											
Capital Expenditures	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1	$0.1
Working Capital	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0
Interest & Other Expense	$1.0	$1.0	$1.0	$0.5	$0.0	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)	($0.5)
Non-Cash Expenses	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)	($1.0)
Capital Adjustment	**$1.1**	**$1.1**	**$1.1**	**$0.6**	**$0.1**	**($0.4)**	**($0.4)**	**($0.4)**	**($0.4)**	**($0.4)**	**($0.4)**
ROIC	*-581.7%*	*-1291.5%*	*-25.3%*	*-1950.6%*	*-27543.1%*	*7571.2%*	*12081.0%*	*11667.3%*	*12897.2%*	*12262.8%*	*12569.6%*
Discounted Cash Flow											
Net Income	$5.4	$13.2	($0.7)	$10.7	$26.5	$24.9	$33.1	$32.0	$35.4	$33.6	$34.5
Depreciation and amortization	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0	$1.0
Net Cash Changes	($1.1)	($1.1)	($1.1)	($0.6)	($0.1)	$0.4	$0.4	$0.4	$0.4	$0.4	$0.4
Post-Tax Operating Cash Flow	**$5.3**	**$13.1**	**($0.8)**	**$11.1**	**$27.4**	**$26.3**	**$34.5**	**$33.4**	**$36.8**	**$35.0**	**$35.9**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**$5.3**	**$13.1**	**($0.8)**	**$11.1**	**$27.4**	**$26.3**	**$34.5**	**$33.4**	**$36.8**	**$35.0**	**$35.9**

Assumptions	
Beta:	1.50
Equity Risk Premium:	7.0%
Risk Free Rate:	2.0%
Firm Risk Premium:	50%
Discount Rate:	**12.5%**

Valuation	
10-Year Model:	$111.1
Terminal Growth:	2%
Terminal Value:	$93.6
CA - CL & Debt:	($10.3)
Firm Value:	**$194.4**

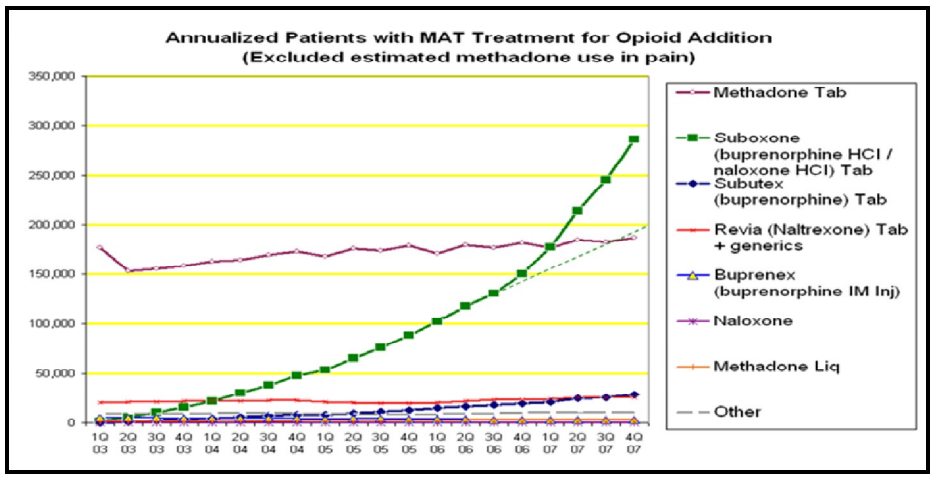
Price Target	
Basic Outstanding:	64.1
Options / Warrants:	12.5
Dilution:	0
Fully Diluted:	76.5
Target Price:	**$2.54**

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

INVESTMENT THESIS

Large Market Opportunity

Sublingual buprenorphine sales are just over $1 billion in the U.S., with another $250 million outside the U.S.



Probuphine has several key advantages over Suboxone. On Titan's second quarter update call, management hosted two of the lead investigators in the PRO-806 phase 3 study. They were Dr. Walter Ling, M.D., Professor of Psychiatry and Director, Integrated Substance Abuse Programs at the David Geffen School of Medicine at UCLA and Dr. Richard N. Rosenthal, M.D., Chairman of Psychiatry at St. Luke's-Roosevelt Hospital Center, a teaching hospital of Columbia University, past president of the American Academy of Addiction Psychiatry. Both doctors expressed their enthusiasm for Probuphine and why they believe it will see meaningful commercial uptake.

We do not see the implant procedure as greatly limiting uptake for Probuphine. Management full acknowledges that there will be some patients adverse to an implantable drug, but we suspect that it will be only a small percent of the patients seeking treatment. In our view, and the views of Dr. Ling and Dr. Rosenthal, Probuphine improves compliance greatly over the once daily oral medication, as well as eliminates the risk for diversion or misuse.

It eliminates the need for monthly visits to the clinic or the need for the physician to actively monitor the patient to make sure dosing is on schedule. Once Probuphine is implanted, the drug goes to work unencumbered for six months. Dr. Rosenthal called Probuphine, "The right drug with the right delivery system."

Opioid addiction is a major health and social issue, especially in the U.S. An estimated 5+ million people worldwide, nearly 4 million of which are in the U.S., are abusing or addicted to opioids. In the U.S. alone, opioid abuse has increased 140% from 1992 to 2003. It's a $10+ billion burden to the U.S. healthcare market.

The World Health Organization estimates that between 4.6 and 5.2 million individuals in the U.S. and Europe use illicit opioids such as heroin, and more than 2.0 million individuals in the U.S. alone are addicted to prescription opioid medications. It is estimated that more than 1.0 million people in the U.S. and Europe currently receive pharmacological treatment for opioid addiction. A six month prescription of Suboxone costs roughly $2,000, with patients averaging duration between 8 and 10 months. At a slight premium price of $2,500 per implant, if Probuphine can capture 10% market share, the drug is a $300+ million opportunity for Titan.

- Estimated 5 million individuals addicted to opioids…
  - 25% seeking treatment (Suboxone does 500,000+ Rx per year)…
    - 10% try Probuphine (six month implant)…
      - Probuphine costs $2500 per implant…
        - 5 million * 25% * 10% * $2500 per implant ~ $300 million

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc.
Income Statement

	2010 E	2011 A	Q1 A	Q2 A	Q3 E	Q4 E	2012 E	2013 E	2014 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$4.7**	**$12.1**
YOY Growth	-	-	-	-	-	-	-	-	*155.0%*
Fanapt Royalty	**$2.5**	**$3.6**	**$1.2**	**$1.4**	**$1.3**	**$1.3**	**$5.2**	**$5.3**	**$5.4**
YOY Growth	-	*42.7%*	*71.5%*	*125.9%*	*33.6%*	*0.5%*	*44.7%*	*2.2%*	*1.9%*
Licensing & Grant Revenue	**$7.6**	**$0.5**	**$0.0**	**$0**	**$0**	**$15.0**	**$15.0**	**$20.0**	**$0**
Total Revenues	**$10.1**	**$4.1**	**$1.3**	**$1.4**	**$1.3**	**$16.3**	**$20.2**	**$30.0**	**$17.5**
YOY Growth	-	*-59.7%*	-	-	-	-	*397.3%*	*48.5%*	*-41.8%*
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100.0%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*
R&D	$12.9	$11.2	$3.1	$2.0	$2.0	$1.5	$8.5	$5.0	$6.0
% R&D	*127.4%*	*275.5%*	-	-	-	-	*42.2%*	*16.6%*	*34.3%*
SG&A	$3.3	$3.4	$1.7	$1.1	$1.1	$1.1	$5.1	$6.0	$7.0
% SG&A	*32.3%*	*82.8%*	-	-	-	-	*25.0%*	*20.0%*	*40.1%*
Operating Income	($6.0)	($10.5)	($3.5)	($1.7)	($1.8)	$13.7	$6.6	$19.0	$4.5
Operating Margin	*0.0%*	*-258.3%*	-	-	-	-	*32.8%*	*63.4%*	*25.6%*
Total Other Income	($0.8)	($4.7)	($1.6)	$0.0	($0.7)	($0.4)	($1.5)	($1.0)	$1.0
Pre-Tax Income	($6.8)	($15.2)	($5.2)	($1.7)	($2.5)	$13.3	$5.1	$18.0	$5.5
Taxes & Other	($1.2)	$0	$0	$0	$0	$0	$0	$2.7	$1.6
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5%*	*15%*	*30%*
Net Income	($5.6)	($15.2)	($5.2)	($1.7)	($2.5)	$13.3	$5.1	$15.3	$3.8
Net Margin	*0.0%*	*-373.7%*	-	-	-	-	*25.4%*	*51.0%*	*21.9%*
Reported EPS	**($0.09)**	**($0.26)**	**($0.09)**	**($0.03)**	**($0.04)**	**$0.19**	**$0.08**	**$0.19**	**$0.05**
YOY Growth	*-6.2%*	*171.5%*	-	-	-	-	*-130.7%*	*143.4%*	*-76.5%*
Weight Ave. Shares Out	59.2	59.3	59.4	65.0	66.2	70.0	65.1	80.0	85.0

Source: Zacks Small-Cap Research, Inc. *Jason Napodano, CFA*

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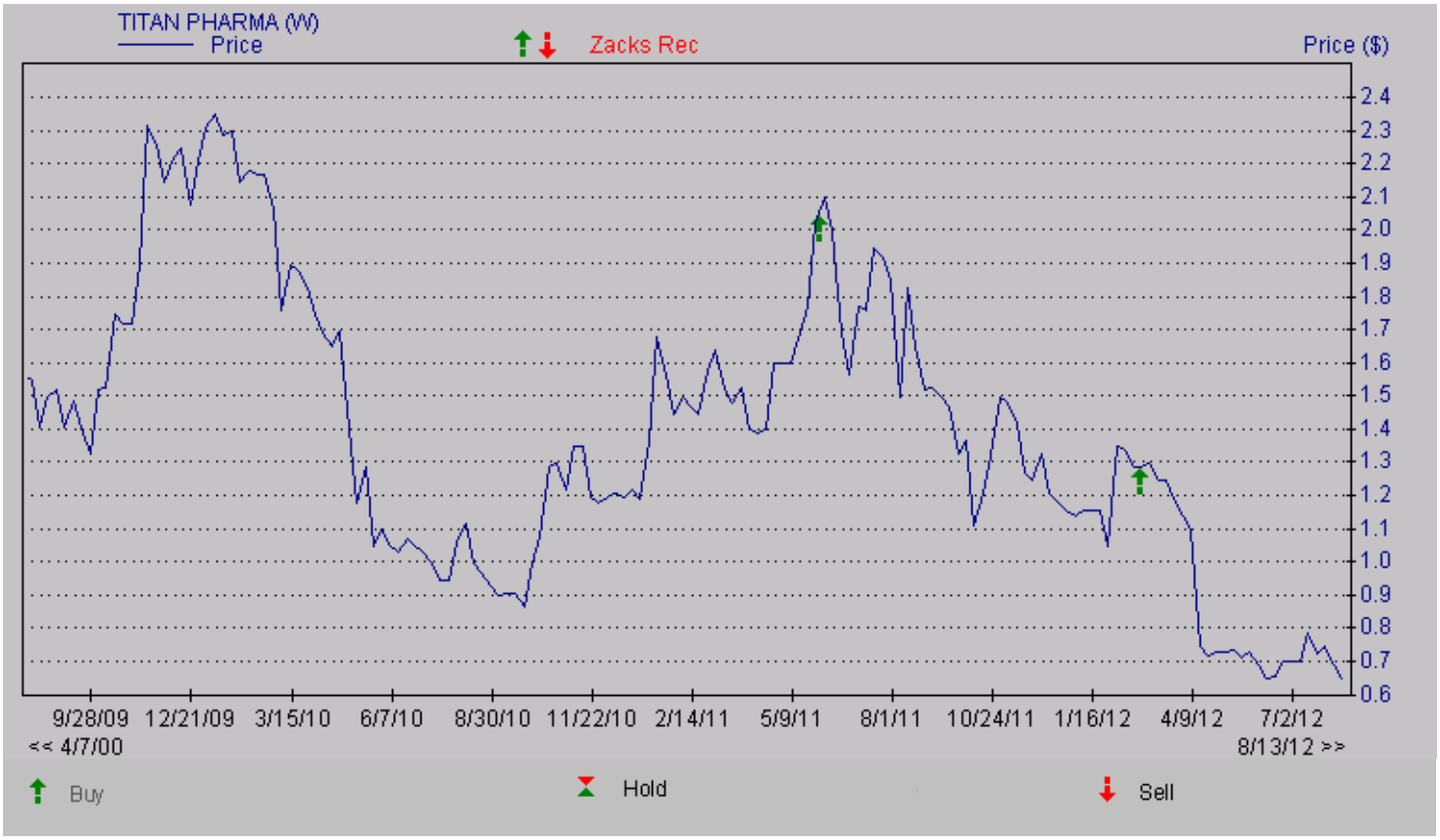
HISTORICAL RECOMMENDATIONS



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