Zacks Small-Cap Research

March 20, 2012
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Titan Pharmaceuticals, Inc. (TTNP-OTC)

TTNP: NDA Planned For Q3-2012…Investors Waiting For Partnership.

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (03/20/12)	$1.28
Target Price	**$3.00**

UPDATE

In February 2012, Titan Pharmaceuticals reported data from the company's six month, open-label, re-treatment program, dubbed PRO-811, with Probuphine. The data are consistent with the previously reported confirmatory phase 3 trial. We think this data completes the necessary clinical work for Probuphine. Management is wrapping up the necessary CMC work to submit to the U.S. FDA, along with the NDA for approval, by the third quarter 2012. The opportunity exists for Titan to seek a priority review on Probuphine.

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 $3 based on our DCF model.

SUMMARY DATA

52-Week High	**$2.16**
52-Week Low	**$1.05**
One-Year Return (%)	**-10.96**
Beta	**9.76**
Average Daily Volume (sh)	**50,605**
Shares Outstanding (mil)	**59**
Market Capitalization ($mil)	**$77**
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	0.1 E	0.1 E	0.1 E	20.1 E	20.4 E
2013					25.9 E
2014					15.1 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	-$0.04 E	-$0.05 E	-$0.04 E	$0.29 E	$0.17 E
2013					$0.21 E
2014					$0.07 E

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

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WHAT'S NEW

NDA Planned For Q3-2012

Titan believes it is on track to file the New Drug Application (NDA) with the U.S. FDA in the third quarter 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 by mid-year.

According to management, the manufacturing facility expansion and qualification for commercial scale production of Probuphine is in process, but has been slightly delayed due to longer than expected lead-time on air handling equipment and the manufacturing of three qualification batches. This should be completed in September 2012. We remind investors that the manufacturing for Probuphine will take place at a cGMP contract manufacturer, DPT Labs, located in San Antonio, TX.

The NDA will be via the FDA's 505(b)(2) pathway for a reformulation of previously approved buprenorphine. 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 the Prescription Drug User Fee Act (PDUFA). If the application is filed in September 2012, Priority Review puts the FDA action date in March 2013. Regular review puts FDA action in July 2013.

…Time To Partner…

Now that Titan has a clear path toward the NDA filing, and potentially an application that the U.S. FDA could consider a Priority Review, the company is pursuing a commercialization partnership. Approval is the ultimate value driver, but we believe that two positive phase 3 trials and a NDA potentially under Priority Review by the end of the third quarter 2012 should provide enough of a road-map with a potential partner to sign a deal later in 2012.

Management has noted being in discussion with a handful of potential commercialization partners. Talks have progressed to the initial term sheet stage. Management continues to work with Woodside Capital Partners and Keelin Reeds Partners in closing a partnership agreement on Probuphine. Woodside is focused on identifying potential partners and introducing them to the Probuphine story. Keelin Reeds is focused on the analytics and valuation of the asset. We recently met with management face-to-face in January 2012.

We think Probuphine, with potential peak sales of $300+ million, could fetch as much as $20 million upfront, with another $20 million 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.

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.

…Cash Becoming A Concern…

Titan exited 2011 with $5.4 million in cash and investments. We project this is enough cash to fund operations to the middle of 2012. With the NDA not expected until the third quarter 2012, a deal will have to get done prior to the NDA filing. If management cannot sign a commercialization partnership in the next two months, we would expect a dilutive offering enough to bridge fund operations to the PDUFA data.

Stock Looks Under-Valued

We see Titan shares as meaningfully under-valued today. Our scenario for Probuphine assumes a new drug application (NDA) during the third quarter of 2012, approval and launch in mid-2013. We expect a U.S. deal around the time of the NDA filing, which should bring upfront cash in the area of $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 $3.00 per 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	$6.5	$16.6	$27.1	$38.0	$45.8	$53.9	$58.7	$63.6	$61.1	$62.3
YoY Growth	-	-	*155%*	*63%*	*40%*	*21%*	*18%*	*9%*	*8%*	*-4%*	*2%*
Licensing & Milestones	$20.0	$20.0	$0	$10.0	$0	$10.0	$0	$0	$0	$0	$0
Revenues (in Millions)	**$20.0**	**$26.5**	**$16.6**	**$37.1**	**$38.0**	**$55.8**	**$53.9**	**$58.7**	**$63.6**	**$61.1**	**$62.3**
CoGS	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*
R&D	*$5.4*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*
SG&A	*$3.6*	*$4.0*	*$4.5*	*$4.5*	*$4.5*	*$4.5*	*$4.5*	*$4.5*	*$4.5*	*$4.5*	*$4.5*
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	$11.0	$17.5	$7.1	$27.6	$28.5	$46.3	$44.4	$49.2	$54.1	$51.6	$52.8
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	**$10.0**	**$16.5**	**$6.1**	**$26.6**	**$27.5**	**$45.3**	**$43.4**	**$48.2**	**$53.1**	**$50.6**	**$51.8**
EBITDA margin	*50.0%*	*62.3%*	*36.7%*	*71.7%*	*72.4%*	*81.2%*	*80.5%*	*82.1%*	*83.5%*	*82.8%*	*83.1%*
Cash Taxes	$0	$0	$0	($2.7)	($4.1)	($13.6)	($13.0)	($14.5)	($15.9)	($15.2)	($15.5)
Tax Rate	*0%*	*0%*	*0%*	*10.0%*	*15.0%*	*30.0%*	*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	*-1000.0%*	*-1591.7%*	*-645.2%*	*-4598.3%*	*-28497.4%*	*11577.2%*	*11104.6%*	*12292.3%*	*13522.2%*	*12887.8%*	*13194.6%*
Discounted Cash Flow											
Net Income	$10.0	$16.5	$6.1	$23.9	$23.4	$31.7	$30.4	$33.7	$37.2	$35.4	$36.2
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	**$9.9**	**$16.4**	**$6.0**	**$24.3**	**$24.3**	**$33.1**	**$31.8**	**$35.1**	**$38.6**	**$36.8**	**$37.6**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Free Cash Flow	**$9.9**	**$16.4**	**$6.0**	**$24.3**	**$24.3**	**$33.1**	**$31.8**	**$35.1**	**$38.6**	**$36.8**	**$37.6**

Assumptions	
Beta:	N/A
Equity Risk Premium:	7.5%
Risk Free Rate:	2.0%
Firm Risk Premium:	50%
Discount Rate:	**13.3%**

Valuation	
10-Year Model:	$128.2
Terminal Growth:	3%
Terminal Value:	$96.2
Net Cash - LT Debt:	($7.4)
Firm Value:	**$217.1**

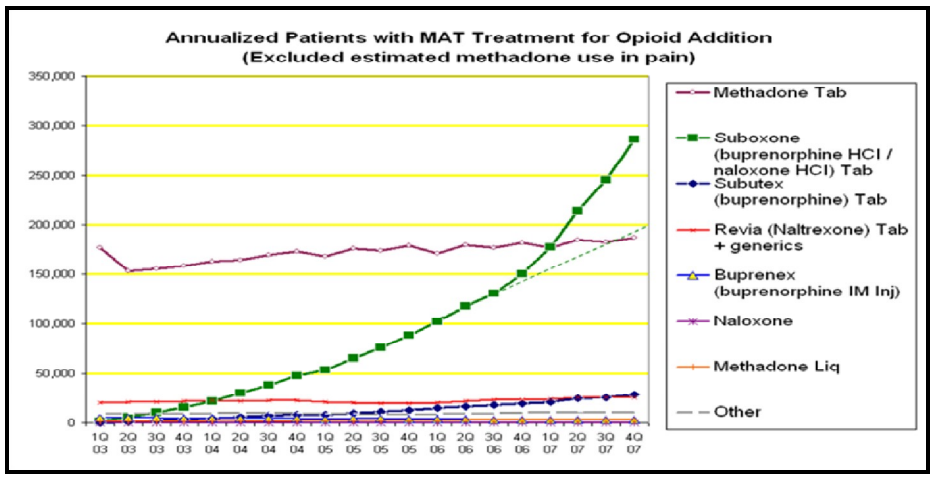
Price Target	
Basic Outstanding:	59.4
Options / Warrants:	13.0
Dilution:	0.0
Fully Diluted:	72.4
Target Price:	**$3.00**

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 E	Q2 E	Q3 E	Q4 E	2012 E	2013 E	2014 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$5.9**	**$15.1**
YOY Growth	-	-	-	-	-	-	-	-	*155.0%*
Fanapt Royalty	**$2.5**	**$3.6**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	*42.7%*	*-100.0%*	*-100.0%*	*-100.0%*	*-100.0%*	-	-	-
Licensing & Grant Revenue	**$7.6**	**$0.5**	**$0.1**	**$0.1**	**$0.1**	**$20.1**	**$20.4**	**$20.0**	**$0**
Total Revenues	**$10.1**	**$4.1**	**$0.1**	**$0.1**	**$0.1**	**$20.1**	**$20.4**	**$25.9**	**$15.1**
YOY Growth	-	*-59.7%*	-	-	-	-	*401.5%*	*27.0%*	*-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	$1.4	$1.5	$1.3	$1.2	$5.4	$5.0	$5.0
% R&D	*127.4%*	*275.5%*	-	-	-	-	*26.5%*	*19.3%*	*33.1%*
SG&A	$3.3	$3.4	$0.9	$0.9	$1.0	$0.8	$3.6	$4.0	$4.5
% SG&A	*32.3%*	*82.8%*	-	-	-	-	*17.6%*	*15.4%*	*29.8%*
Operating Income	($6.0)	($10.5)	($2.2)	($2.3)	($2.2)	$18.1	$11.4	$16.9	$5.6
Operating Margin	*0.0%*	*-258.3%*	-	-	-	-	*55.9%*	*65.3%*	*37.0%*
Total Other Income	($0.8)	($4.7)	($0.4)	($0.4)	($0.4)	($0.4)	($1.5)	($1.0)	$1.0
Pre-Tax Income	($6.8)	($15.2)	($2.6)	($2.7)	($2.6)	$17.7	$9.9	$15.9	$6.6
Taxes & Other	($1.2)	$0	$0	$0	$0	$0	$0	$2.4	$2.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5%*	*15%*	*30%*
Net Income	($5.6)	($15.2)	($2.6)	($2.7)	($2.6)	$17.7	$9.9	$13.5	$4.6
Net Margin	*0.0%*	*-373.7%*	-	-	-	-	*48.5%*	*52.2%*	*30.6%*
Reported EPS	**($0.09)**	**($0.26)**	**($0.04)**	**($0.05)**	**($0.04)**	**$0.29**	**$0.17**	**$0.21**	**$0.07**
YOY Growth	*-6.2%*	*171.5%*	-	-	-	-	*-164.5%*	*25.9%*	*-68.3%*
Weight Ave. Shares Out	59.2	59.3	59.5	59.5	60.0	60.5	59.9	65.0	70.0

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

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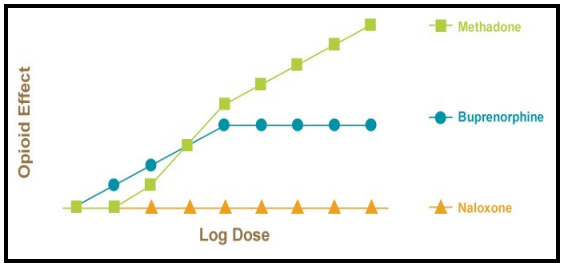
APPENDIX

…Background on buprenorphine…

Buprenorphine is a synthetic derivative of opium, chemically similar to both morphine and codeine, but has stimulatory rather than depressant effects. Buprenorphine is 25-50X more potent than morphine and is sometimes used recreationally by insufflations (crushing and inhaling the powder).

Buprenorphine is commonly used to treat addiction to heroin, and has proven superior in its efficacy and convenience to methadone. Withdrawal from buprenorphine after short-term use is generally far milder than other potent opioids, but can have a longer duration of abuse. The drug has a pharmacologic ceiling effect, which provides an increased safety margin when compared to methadone. As a result, the drug is now generally recognized as the gold standard for the treatment of opioid addiction. There are an estimated 3.7 million people addicted to opioids in the U.S., over 80% of which are prescription drugs.

	U.S.	EU
All Opioid Addiction	**3.7M**	**1.8M**
Heroin	0.6M	1.6M
Prescription Drugs	3.1M	0.2M



The product was first marketed in 1980 by British firm, Reckitt & Colman as an analgesic, available as Temgesic 0.2 mg sublingual tablets, and as Buprenex in a 0.3 mg/ml injectable formulation. In October 2002, the U.S. FDA approved Subutex as high-dose (2 mg & 8 mg) sublingual pill preparations indicated for detoxification and long-term replacement therapy in opioid dependency. As a result, the drug is now predominantly used for this purpose. Approval in France first came in 1997, and has since followed to the majority of the EU. Buprenorphine is a Schedule III controlled substance under the United Nations' Convention on Psychotropic Substances.

In October 2002, the U.S. FDA also approved Suboxone, a novel formulation of buprenorphine and naloxone, to increase the deterrence of abuse through intravenous injection. Naloxone is an opioid antagonist that blocks the high or euphoric effects for opioids such as heroine that leads to withdrawal symptoms. In October 2009, the FDA approved a generic preparation of 2 mg and 8 mg sublingual dosages of buprenorphine. Demand was so high that pharmacies began to run out of supply and Roxane Labs, the first generic filer, was unable to meet demand. In April 2010, the FDA approved a second supplier in Teva Pharmaceutical. Reckitt is now marketing a Suboxone Film, approved in August 2010, to counter generic the pending availability to the sublingual tablet.

In 2001, Grunenthal introduced Transtec (buprenorphine transdermal patch) in Europe for the treatment of chronic pain. The product is available as a 35, 52.5 and 70 ug (micrograms) per hour transdermal patches that deliver the dose over ninety-six hours. It is also used for the treatment of moderate to severe cancer pain and severe non-cancer pain not responding to non-opioids. Purdue Pharma markets Butrans in the U.S., a 5, 10, and 20 ug, 7-day transdermal patch for the management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time. A similar transdermal product is marketed by collaboration between Mundipharma and Grunenthal in Australia under the name Norspan. We note that buprenorphine is not administered orally due to very high first-pass metabolism. The transdermal patch products can typically be worn for 3 to 7 days.

BioDelivery Sciences is currently in phase 3 trials with BEMA buprenorphine. The company's BEMA technology utilizes a small, bioerodible polymer film for application to the mucosal membranes (inner lining of cheek). BEMA films were designed to rapidly deliver a dose of drug across the mucous membranes for time sensitive conditions or to facilitate administration of drugs with poor oral (pill) absorption. BEMA buprenorphine is being designed to eliminate abuse potential by crushing sublingual tablets, a similar concept to Titan's Probuphine. However, BDSI's BEMA product requires daily dosing whereas Probuphine is a six month implant.

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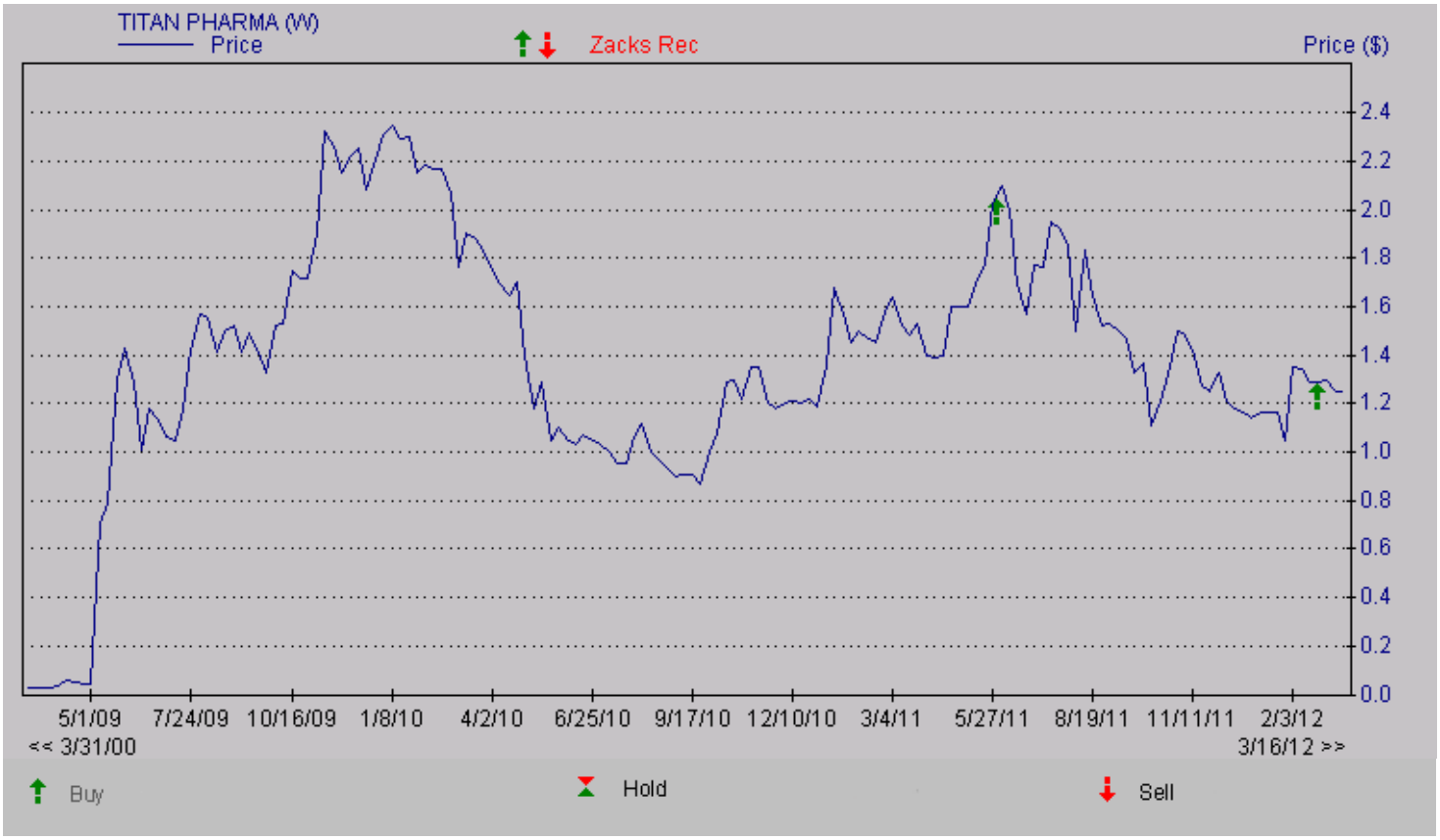
HISTORICAL RECOMMENDATIONS



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