Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-OTC)

TTNP: It's Time To Find A Partner For Probuphine…

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (08/16/11)	$1.77
Target Price	**$3.50**

UPDATE

This morning Titan released additional positive data from its second phase 3 confirmatory trial on Probuphine. The data looks fantastic, with strong statistical significance vs. placebo and non-inferiority to a blockbuster drug in Suboxone. We highlight the data in our report, as well as update timelines for the planned FDA meeting and NDA filing.

Our valuation incorporates a sum-of-parts (NPV) analysis on the royalties from Fanapt ($0.50 per share) and the risk-adjusted market potential for Probuphine at this stage in its development ($3.00 per share). We are making an aggressive call to buy Titan now that the key clinical trial hurdle has been cleared. We expect a partnership on Probuphine in the next year, with FDA approval in 2013.

SUMMARY DATA

52-Week High	**$2.16**
52-Week Low	**$0.87**
One-Year Return (%)	**76.19**
Beta	**10.84**
Average Daily Volume (sh)	**152,153**
Shares Outstanding (mil)	**59**
Market Capitalization ($mil)	**$110**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**2**
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 2011 Estimate	**N/A**
P/E using 2012 Estimate	**N/A**
Zacks Rank	**1**

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)
2010	2.4 A	1.3 A	3.6 A	2.7 A	10.1 A
2011	0.9 A	0.7 E	0.9 E	1.1 E	3.7 E
2012					14.8 E
2013					23.8 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.01 A	-$0.03 A	-$0.01 A	-$0.05 E	-$0.09 E
2011	-$0.08 A	-$0.12 A	-$0.06 E	-$0.04 E	-$0.29 E
2012					$0.03 E
2013					$0.12 E

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

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WHAT'S NEW

Financial Review

On August 16, 2011, Titan Pharmaceuticals reported financial results for the second quarter 2011. Total revenues in the quarter were $0.7 million, and consisted of $0.6 million in royalties on Fanapt sales at Novartis and $0.1 million in grant revenues from the NIH (for Probuphine) and the SBIR (for ProNeura).

Fanapt sales at Novartis were $7 million in the second quarter 2011, below our estimate of $12 million. As a reminder, Titan is eligible to receive 8-10% royalties on Fanapt sales (8% below $100 million), of which Titan pays a sub-royalty of 2.5% to Deerfield Management relating to the April 2011 $20 million loan (discussed below). Fanapt sales have disappointed since the launch. We have lowered our peak estimate for Fanapt sales at Novartis to $125 million in 2015 (down from $200 million). Royalties on Fanapt account for $0.50 of our $3.50 valuation. We think the opportunity exists for management to enter into a royalty-sale transaction in the next few quarters to raise non-dilutive capital.

Operating expenses were in-line with expectations in the second quarter at $4.9 million. Net loss in the second quarter totaled $7.0 million, of ($0.12) per share, which included $2.8 million in other expenses - $1.0 million of interest expense resulting from the Deerfield transaction in April 2011 and $1.6 million non-cash loss related to an increase in the fair value of the Deerfield warrant liability. Net loss was larger than expected based on these charges. We had forecasted EPS of ($0.06).

- We remind investors that during the second quarter, Titan entered into an agreement with Deerfield Management that provides Titan with $20 million in financing through a five year senior secured credit facility. Interest will accrue on the outstanding balance until maturity at a rate of 8.5% per annum, which is payable on a quarterly basis. The facility is repayable over five years, with 10% of the principal amount due on the first anniversary, 15% on the second anniversary, and 25% of the principal amount on each of the next three anniversaries. Management can elect to pre-pay the outstanding balance at any time at 110% of the remaining principal amount. Deerfield Management has a repayment right at 110% of the principal amount upon a major transaction (which includes but is not limited to the sale of Fanapt or Probuphine). In conjunction with the financing, Titan has agreed to issue six year warrants to purchase 6 million shares of common stock at an exercise price of $1.57 per share. Deerfield Management will also receive 2.5% of the global net sales of Fanapt subject to a repurchase right by Titan. In April 2011, Titan repaid its current outstanding loan with Oxford Finance Corp totaling roughly $8 million. Management used the proceeds from the Deerfield credit facility to payback Oxford.

Titan exited the second quarter with $6.1 million in cash. We project this is enough cash to fund operations into the first quarter 2012. This is right around the time of the NDA filing on Probuphine. Management's goal is to find a commercialization partner on Probuphine to generate non-dilutive cash. If management cannot get a deal done before the end of the year, we would expect a dilutive offering. We note the 6 million warrants outstanding at Deerfield offer a potential cash influx to management should Deerfield look to exercise them (~$9.4 million). However, as of August 2011, none of these warrants have been exercised.

INVESTMENT THESIS

Second Phase 3 On Probuphine Hits!

On July 11, 2011, Titan Pharma announced positive results from its phase 3 trial, PRO-806, evaluating Probuphine in treating patients with opioid dependence. PRO-806 was the second, confirmatory, phase 3 program evaluating Probuphine vs. placebo for safety and efficacy. The phase 3 clinical trial was a randomized, placebo and active-controlled, multi-center study conducted at 20 sites in the U.S. that treated 287 patients, aged 18 to 60 years across three dosing arms: Probuphine (114 patients), the approved and widely-used sublingual formulation of buprenorphine, Suboxone, (119 patients) and placebo implants (54 patients). Patients were treated for up to 24 weeks and the Probuphine and placebo dosing arms were double-blinded, while the Suboxone arm was open-label.

The trial had two primary analyses:

1) Cumulative Distribution Function of the percentages of opioid-negative urines (CDF-ONU) over the 24-week treatment period ➔ Results were statistical significance at p<0.0001 vs. placebo, and were consistent with the previously reported phase 3 data (from PRO-805), and published in JAMA, October 2010.

   In fact, in August 2011, management provided some additional color on the CDF-ONU endpoint, breaking down the 24-week period into two sections, weeks 1-16 and weeks 17-24. The statistical significance for weeks 1-16 was p<0.0001, whereas for weeks 17-24 it was p=0.0002.

2) Cumulative Distribution Function of the percentages of opioid-negative urines incorporating patient self-reported opioid use over the 24-week treatment period ➔ Results were statistical significance at p<0.0001 vs. placebo.

Probuphine demonstrated statistical and clinical superiority over placebo for the 24-week treatment period in the mean percentages of urine samples negative for illicit opioids, 36% vs. 14% (p<0.0001). Probuphine treatment resulted in significant improvement in clinician-rated global severity of opioid dependence (p=0.0003) and clinician-rated global improvement in opioid dependence (p=0.0002) vs. placebo at the end of the 24-week treatment period.

Probuphine also met a key trial secondary objective by demonstrating non-inferiority to Suboxone (12-16 mg) over the 24-week treatment period. There was no statistically significant difference between Probuphine and Suboxone on the clinician-rated global severity (p=0.7831) and clinician-rated global improvement (p=0.9881). We remind investors that Suboxone is used by over 500,000 patients in the U.S. each year, with annualized sales over $1 billion. Worldwide, Suboxone is a $1.2 billion drug.

Pro-806	Probuphine (n=114)	Suboxone (12-16mg) (n=119)	Placebo (n=54)
Negative Urine Samples	36%	35%	14%
Trial Retention	64%	64%	26%

The trial further demonstrated that Probuphine was well tolerated, with an overall safety profile similar to that seen in previous studies. We present the most common adverse events below:

Headache	13.2%	16.0%	9.3%
Up Resp. Tract Infection	8.8%	9.2%	7.4%
Depression	8.8%	2.5%	3.7%
Insomnia	7.9%	13.4%	14.8%
Sore Throat	7.0%	3.4%	1.9%
Nausea	6.1%	6.7%	1.9%
Vomiting	6.1%	4.2%	1.9%

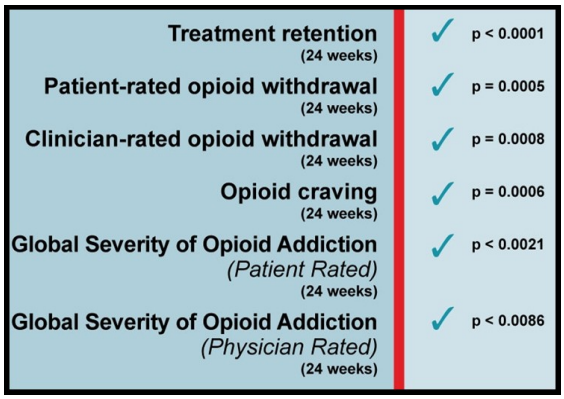
Titan has been invited to present the results from the PRO-806 phase 3 trial during a plenary session on September 10, 2011, and in a poster presentation on September 8, 2011 at the 13th annual meeting of the International Society of Addiction Medicine (ISAM) in Oslo, Norway. We remind investors that Titan is still conducting an open-label, 6-month re-treatment trail, PRO-811, for patients that completed PRO-806. As of August 2011, management noted that over 80% of the eligible patients have elected to enroll in the study. Data is expected from PRO-811 later this year or in early 2011.

…Confirms Previous Positive Data With First Phase 3 Trial…

Titan successfully completed the first phase 3 study (Study Pro-805) and presented the data at U.S. and international scientific meetings held during 2008 and 2009. Pro-805 enrolled a total of 163 subjects (2-1 randomization) from 18 clinical sites all in the U.S. participated in the program.

In this study, Probuphine showed a clinically and statistically significant difference over placebo in illicit opioid use as measured by urine testing performed three times per week, for the entire duration of the 6 month treatment (p=0.0117). As agreed with the FDA, the statistical analysis was an evaluation of the Cumulative Distribution Function of the percent opioid negative urines (CDF-ONU) analyzed using the Wilcoxon Rank Sum Test conducted twice, specifically, the primary endpoint compared the CDF-ONU of percent negative urines for weeks 1-16 (p=0.0361) and the key secondary endpoint compared the CDF-ONU of the percent negative urine samples for weeks 17-24 (p=0.0004).

We note that approximately 66% of the Probuphine patients completed the study vs. only 31% on the placebo. There is often a mixed bag of reasons why patients discontinue, from lack of response to such a great response that patients opted out of the return visits prior to the trials completion. We think it is important to note, however, that there were no treatment failures in the test group, vs. approximately 31% on the placebo. We believe this evaluation demonstrates the effectiveness of Probuphine compared to placebo for the entire treatment period, as well as emphasizes that patients who are compliant to treatment with Probuphine show even better results (compared to placebo) over time.



Additional secondary analysis demonstrated things like, comparison of the mean percent negative urines, retention in treatment, patient and clinician opioid withdrawal, opioid craving, and patient and clinician rated improvement and disease severity all showed highly statistically significant differences in favor of Probuphine.

We believe this emphasizes the clear effectiveness of the product, and should help drive sales in the real-world setting. Safety parameters including adverse events, vital signs, and clinical laboratory testing demonstrated that Probuphine was generally well tolerated in this patient population. Data from this study has been published in the Journal of American Medical Association (JAMA) in October 2010.

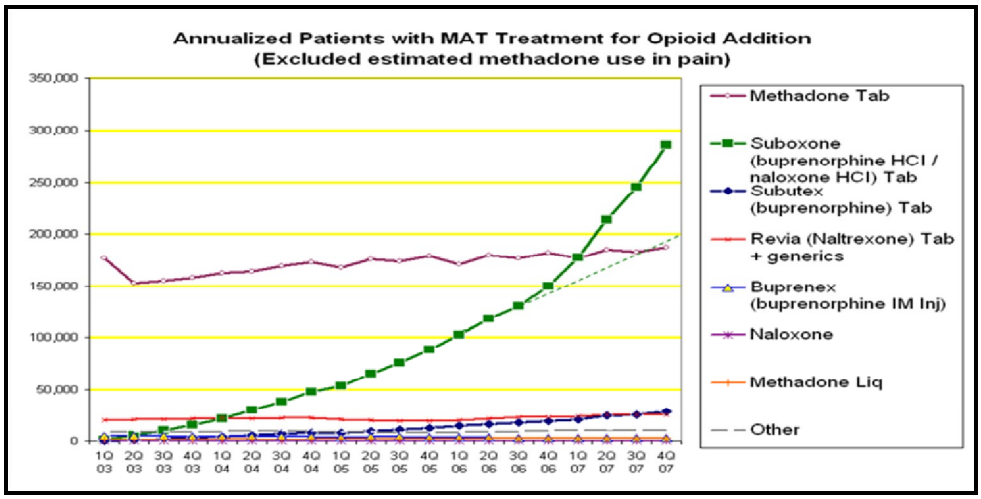
Following completion of the Pro-805 program, patients were eligible to enroll into a six-month, open-label, multi-center retreatment trial, dubbed Pro-807. This trial was completed in the second quarter 2009. We note that 70% of the eligible test subjects from Pro-805 elected to participate in the open-label safety extension. Approximately 74% of these patients completed the 6 month follow-up. Results show that Probuphine was safe and well-tolerated. During Pro-805 and Pro-807, implant insertion and removal procedures were safe and well-tolerated. Results from these studies have been presented at the American Society of Addiction Medicine (ASAM), the California Society of Addiction Medicine (CSAM), and the American College of Neuropsychopharmacology (ACNP) meeting all in 2009.

…Pre-NDA Meeting In October 2011…

Titan now has two positive phase 3 trials, along with open-label follow-up studies, and statistically significant non-inferiority to a blockbuster drug in Suboxone. The company has amassed data from roughly 290 patients at 6-months and 110 patients at 12-months. Management plans to meet with the U.S. FDA in the next few months (guidance is around October 2011) for a pre-NDA meeting. We expect an update following the minutes of this meeting in November or December 2011.

…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 $2000, with patients averaging duration between 8 and 10 months. At a similar price of $2000 per implant, if Probuphine can capture 10% market share, the drug is a $350 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)…
      - 40% re-treat for another six months…
        - Probuphine costs $2000 per implant…
          - 5 million * 25% * 10% * 1.40x * $2000 per implant ~ $350 million

We assume that Titan will secure a commercialization partner in the next several months, which will provide the company with an upfront licensing payment (we estimate $25 million), future regulatory and sales milestone payments (we estimate $100 million), and royalties on sales of Probuphine (we estimate 20%). On the second quarter conference call, Titan announced that it has engaged Woodside Capital Partners, LLC and Keelin Reeds Partners, LLC as a team to assist the company in business development activities for Probuphine.

VALUATION & RECOMMENDATION

Stock Looks Under-Valued

We see Titan shares as meaningfully under-valued today. We believe that Fanapt alone is worth $0.50 per share based on the future cash royalty payments. As a reminder, Titan has no ongoing costs associated with these royalties besides the credit facility payment to Deerfield Management, so the net amount is pure cash income to the company. The cash from Fanapt royalties helps management fund general corporate expenses. We see Fanapt royalties at $3.2 million in 2011, growing to over $10 million per year around the time of the patent expiration in April 2017. After backing out the 2.5% sub-royalty to Deerfield, the cumulative net present value of these cash flows, assuming a modest 10% discount rate, is $30 million. Based on 60 million shares outstanding, the Fanapt royalty is worth approximately $0.50 per share.

Our scenario for Probuphine assumes a new drug application (NDA) in early 2012, approval in late 2012, with a launch in early 2013. We expect a U.S. deal around the time of the NDA filing, which should bring upfront cash in the area of $25 million, a similar approval milestone in late 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 $180 million, or $3.00 per share. We are using a more aggressive 17.5% discount rate for these cash flows. This is similar to the company's cost of capital based on the March 2011 financing.

Titan exited the second quarter 2011 with $6.1 million in cash. We forecast this will be enough to fund operations into the first quarter 2012. Therefore, a deal with upfront cash is important for later this year. If not, Titan may need to raise $10 million or so to keep timelines on track, as well as continue to negotiate with partners from a position of strength. We believe the company only needs an estimated $10 million to make it to cash flow positive operations based on Fanapt and Probuphine royalty payments.

Titan Pharma Sum-Of-Parts Value	
Fanapt Royalties	$30 Million
Probuphine Value	$180 Million
ProNeura Technology	$10 Million
Cash To Breakeven	($10) Million
Total Firm Value	**$220 Million**
Shares Outstanding	60 Million
Price Per Share	**$3.50**

We note that as part of the Deerfield financing in April 2011, Deerfield was issued six year warrants to purchase 6 million shares of common stock at an exercise price of $1.57 per share. If Deerfield begins to exercise these warrants over the next several months, it could provide cash to Titan to fund operations beyond the current guidance. As of yet, Deerfield has not exercised any of its warrants on the stock.

Upcoming Events

EVENTS TO WATCH	TIMING
Data presentation at NIDA International Forum	June 2011
Top-line data from phase 3 (confirmatory) Pro-806 trial	July 2011
Additional Data from phase 3 Pro-806 trial	August 2011
Data presentation at International Society of Addiction Medicine	September 2011
Meet with U.S. FDA for pre-NDA meeting	October-2011
Data from open-label Pro-811 safety re-treatment study	Q4-2011
Data presentation on Pro-806	Q4-2011
Sign commercialization partnership on Probuphine	Q4-2011
Data presentation at American Academy of Addiction Psychiatry	December 2011
File U.S. NDA on Probuphine	Q1-2012
U.S. FDA NDA acceptance	Q2-2012
U.S. FDA PDUFA on Probuphine	Q4-2012 / Q1-2013
Launch Probuphine in the U.S.	Q1-2013

Source: Zacks Investment Research, Inc.

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc.
Income Statement

	2009 A	2010 E	Q1 A	Q2 A	Q3 E	Q4 E	2011 E	2012 E	2013 E	2014 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$7.0**	**$16.0**
YOY Growth	-	-	-	-	-	-	-	-	-	*128.6%*
Fanapt Royalty	**$0**	**$2.5**	**$0.7**	**$0.6**	**$0.8**	**$1.0**	**$3.2**	**$4.8**	**$6.8**	**$8.4**
YOY Growth	-	-	*-56.7%*	*994.5%*	*102.0%*	*154.9%*	*25.7%*	*52.0%*	*41.7%*	*23.5%*
Licensing & Grant Revenue	**$0.1**	**$7.6**	**$0.2**	**$0.1**	**$0.1**	**$0.1**	**$0.5**	**$10.0**	**$10.0**	**$10.0**
Total Revenues	**$0.1**	**$10.1**	**$0.9**	**$0.7**	**$0.9**	**$1.1**	**$3.7**	**$14.8**	**$23.8**	**$34.4**
YOY Growth	-	-	-	-	-	-	*-63.5%*	*301.8%*	*60.8%*	*44.5%*
CoGS	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
Product Gross Margin	*100%*	*100.0%*	-	-	-	-	*100.0%*	*100.0%*	*100.0%*	*100.0%*
R&D	$2.5	$12.9	$3.7	$3.9	$3.0	$2.5	$13.2	$8.0	$10.0	$10.0
% R&D	-	*127.4%*	-	-	-	-	*358.0%*	*54.1%*	*42.0%*	*29.1%*
SG&A	$3.4	$3.3	$0.8	$0.9	$0.9	$0.9	$3.5	$3.6	$4.0	$4.5
% SG&A	-	*32.3%*	-	-	-	-	*96.1%*	*24.3%*	*16.8%*	*13.1%*
Operating Income	($5.8)	($6.0)	($3.6)	($4.2)	($3.0)	($2.3)	($13.0)	$3.2	$9.8	$19.9
Operating Margin	*0%*	*0.0%*	-	-	-	-	*-354.1%*	*21.6%*	*41.2%*	*57.8%*
Total Other Income	($0.1)	($0.8)	($0.9)	($2.8)	($0.3)	($0.4)	($4.4)	($1.5)	($1.0)	$1.0
Pre-Tax Income	($5.9)	($6.8)	($4.5)	($7.0)	($3.3)	($2.7)	($17.5)	$1.7	$8.8	$20.9
Taxes & Other	$0	($1.2)	$0	$0	$0	$0	$0	$0	$1.3	$6.3
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*5%*	*15%*	*30%*
Net Income	($5.9)	($5.6)	($4.5)	($7.0)	($3.3)	($2.7)	($17.5)	$1.7	$7.5	$14.6
Net Margin	*0%*	*0.0%*	-	-	-	-	*-474.1%*	*11.5%*	*31.4%*	*42.5%*
Reported EPS	**($0.10)**	**($0.09)**	**($0.08)**	**($0.12)**	**($0.06)**	**($0.04)**	**($0.29)**	**$0.03**	**$0.12**	**$0.22**
YOY Growth	-	*-6.2%*	-	-	-	-	*211.8%*	*-109.2%*	*329.7%*	*89.7%*
Weight Ave. Shares Out	58.5	59.2	59.2	59.3	59.3	59.5	59.3	62.5	64.0	66.0

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

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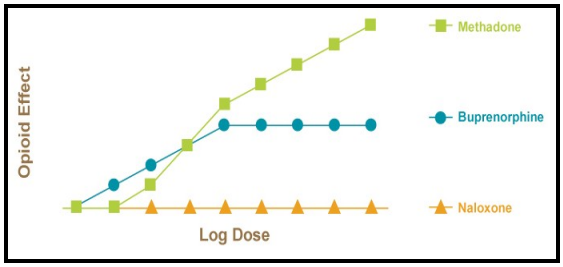
APPENDIX

…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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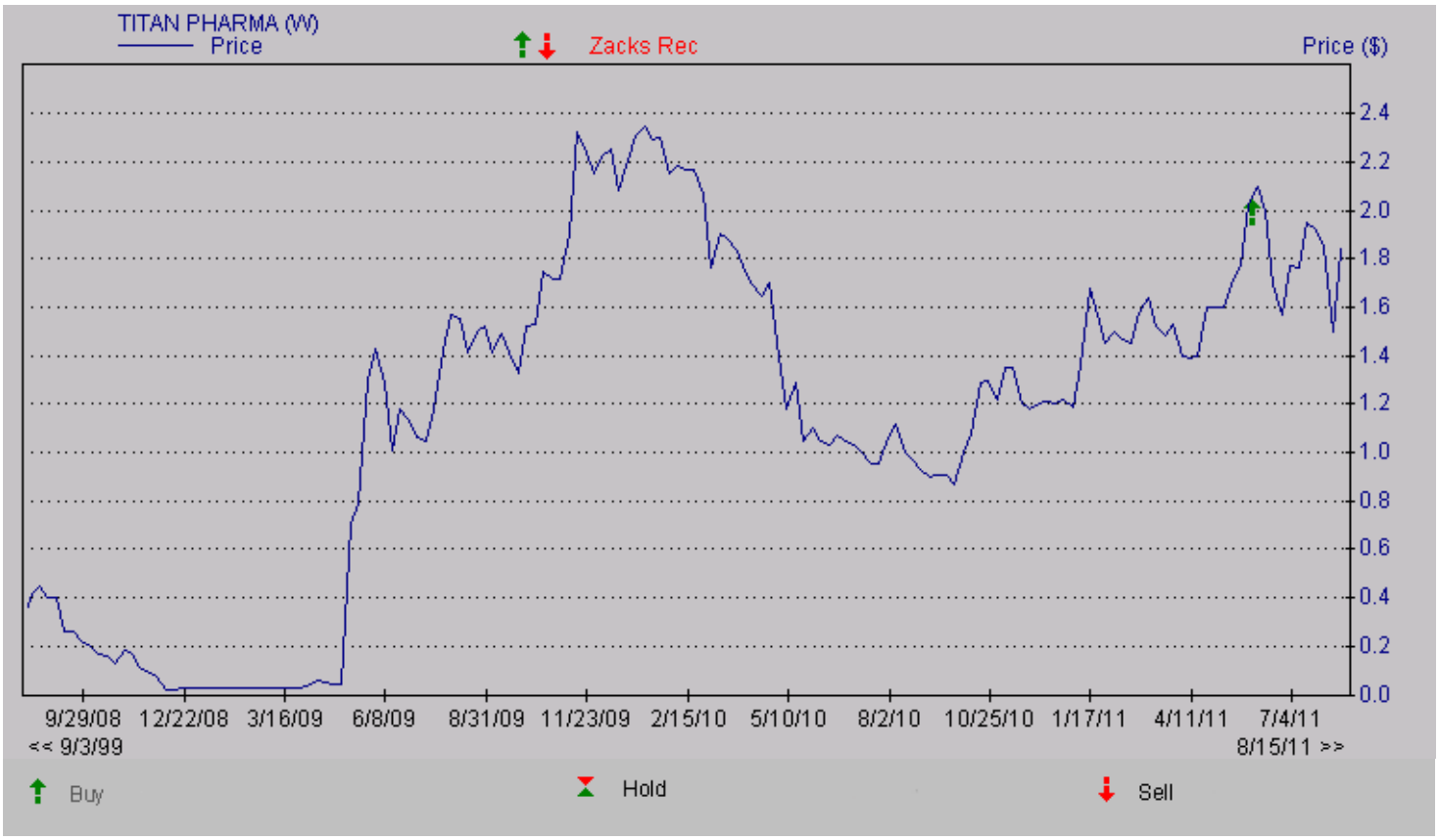
HISTORICAL ZACKS RECOMMENDATIONS



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