Zacks Small-Cap Research

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Titan Pharmaceuticals, Inc. (TTNP-OTC)

TTNP: FDA Issues Harsh Complete Response Letter On Probuphine…

Current Recommendation	**Buy**
Prior Recommendation	N/A
Date of Last Change	06/01/2011
Current Price (05/01/13)	$0.44
Target Price	**$1.00**

UPDATE

On April 30, 2013, The U.S. FDA issued a complete response letter to Titan Pharmaceuticals with respect to the new drug application for Probuphine, the company's subdermal implant for the maintenance treatment of opioid dependence in adult patients. The CRL states the FDA cannot approval the application in its present form, and requests additional data supporting the efficacy or use of Probuphine. Concerns mainly revolve around dosing, dosage, and human factors testing associated with the insertion and removal. The CRL also included recommendations regarding product labeling and the implementations of the Risk Evaluation and Mitigation Strategy (REMS). We believe Titan holds roughly $12 million in cash as of April 30, 2013. We expect Titan and commercial partner Braeburn to push forward with Probuphine, although it could be tough sledding for the next 12 months.

SUMMARY DATA

52-Week High	**$2.48**
52-Week Low	**$0.65**
One-Year Return (%)	**133.80**
Beta	**9.82**
Average Daily Volume (sh)	**560,548**
Shares Outstanding (mil)	**82**
Market Capitalization ($mil)	**$136**
Short Interest Ratio (days)	**0.25**
Institutional Ownership (%)	**18**
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 2013 Estimate	**N/A**
P/E using 2014 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)
2012	1.3 A	1.4 A	1.2 A	3.3 A	7.1 A
2013	3.1 E	3.2 E	3.3 E	3.3 E	12.9 E
2014					10.0 E
2015					2.5 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2012	-$0.09 A	-$0.03 A	-$0.12 A	-$0.01 A	-$0.15 A
2013	-$0.01 E	$0.01 E	$0.00 E	-$0.01 E	-$0.01 E
2014					-$0.03 E
2015					-$0.09 E

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

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WHAT'S NEW

FDA Issues Complete Response Letter

On April 30, 2013, Titan Pharmaceuticals announced the U.S. FDA had issued a complete response letter (CRL) to its new drug application (NDA) for Probuphine, the company's investigational subdermal implant for the maintenance treatment of opioid dependence in adult patients. The CRL states that the FDA cannot approve the application in its present form. The CRL notes concerns with the efficacy and use of Probuphine and requests additional data before approval can be granted. Below we highlight the four issues noted in the CRL.

Issue – 1: The ability of Probuphine to provide opioid blockade of relevant doses of agonists

The FDA is clearly throwing a curveball at Titan with this request. Buprenorphine is not a new molecule to the FDA with a curious mechanism of action. Buprenorphine is a mixed agonist / antagonist, blocking the activity of other opiates and inducing withdrawal in opiate dependent individuals who are currently physically dependent on another opiate like heroin or oxycodone. Data shows that buprenorphine binds strongly to receptors in the brain compared to other opioids such as heroin, making it more difficult for addicts to experience a euphoric high. This effect is present even at low dosages, with as little as 2 mg enough to produce a blocking effect. High doses of buprenorphine, at >32 mg, is enough for the drug to become a full agonist; i.e., it not only completely blocking or reversing opiate effects from other opioids, but also itself. None of this information should be new to the FDA.

Titan's responsibility with its new drug application (NDA) for Probuphine should be to show clear signs of clinical efficacy and safety. Titan was called in front of the FDA's Psychopharmacologic Drugs Advisory Committee meeting on March 21, 2013 to specifically address the efficacy and safety of its drug. What the FDA wants to know now seems tied to the dosing of Probuphine and the plasma levels of the drug given the six month implant vs. daily peak and trough plasma levels with Suboxone (sublingual buprenorphine HCl + naloxone HCl). This issue ties directly into the second issue which we discuss in greater detail below.

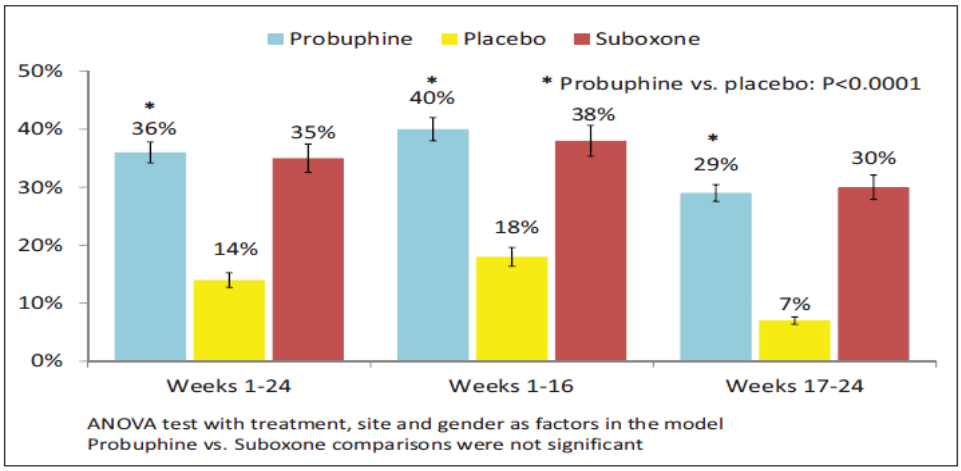
Issue – 2: The effect of higher doses of Probuphine, ideally doses more closely approximating the blood plasma levels associated with sublingual doses of buprenorphine of 12 to 16 mg / day

The FDA is asking Titan to study higher doses of Probuphine that more closely approximate the blood plasma levels associated with 12 to 16 mg / day of buprenorphine. This is a surprising request considering Titan designed the Probuphine implant so that 4 rods is roughly equivalent in efficacy to 16 mg / day. Now the FDA wants to know how it compares on a plasma level (see the first issue noted above).

Probuphine was designed so that each rod delivers 20 mg of buprenorphine over six months with controlled release. However, according to the data from Titan's two phase 3 studies (PRO-805 and PRO-806), a good percent of Probuphine patients both required supplemental sublingual buprenorphine and / or a fifth rod implant. Below is a snap-shot of the data from the clinical study, which includes data from the two open-label extension studies (PRO-807 and PRO-811).

Study	Treatment Group	Subjects Requiring Supplemental SL Buprenorphine	Subjects Requiring A Fifth Implant of Probuphine
PRO-805	Probuphine	62.0%	20.4%
	Placebo	90.9%	58.2%
PRO-806	Probuphine	39.5%	21.9%
	Placebo	66.7%	38.9%
	Suboxone	5.9%	N/A
PRO-807	Probuphine	41.9%	9.7%
PRO-811	Probuphine	20.0%	11.0%

The data above clearly show that more patients on placebo required supplemental buprenorphine than patients on Probuphine; but, perhaps that is not a fair comparison? The FDA asks that companies run randomized, placebo-controlled clinical trials. Titan did this. But in this case, there is an existing product on the market, Suboxone, from which Titan is attempting to capture market share. Clearly far more patients on Probuphine required "help" than those on Suboxone. And when we look at the primary endpoint of the PRO-806 study, we see that the outcome of the two drugs is nearly identical (see table below):



Based on the data from PRO-806, Probuphine is as effective as Suboxone, but patients will still require supplemental Suboxone help. The Probuphine implant is 2.5 mm thick x 26 mm long. We note that is smaller than the Norplant birth control implant at 2.4 mm x 34 mm, or the Norplant II (Jadelle) implant 2.5 mm x 43 mm. Perhaps instead of testing a fifth implant, Titan can extend the length of each Probuphine implant by 6 to 8 mm.

Although this sounds like an easy fix, extending the length of the implant would require additional clinical testing. Nevertheless, it seems as though this is what the FDA wants. Titan's stance is that constant (stable) buprenorphine delivered via the six month implants from Probuphine is equivalent to daily Suboxone, even though the plasma levels are far less. Management believes the peaks and troughs of daily dosing for Suboxone is what limits its efficacy. So what the FDA seems to be asking Titan about here is – what kind of efficacy results can be obtained if the dose of Probuphine is increased to plasma levels equivalent to 12 – 16 mg? This could potentially limit the need for patients to require supplemental Suboxone altogether.

Bulls can interpret this request as a signal that the FDA likes the data they've seen on Probuphine, and now wants more. The FDA is swinging for the fences. Imagine what kind of results we can get IF… However, Bears can clearly argue, the FDA is not satisfied with the data, and thinks this product falls short of truly effective at the doses Titan proposed in the NDA.

The FDA is asking this question despite the fact that it essentially asked the Advisory Committee the same thing. Question # 1 to the committee asked, "*Please comment on whether the Applicant conducted adequate dose exploration in the development program to determine the most effective dose."* The committee voted 10 YES to 5 NO in response to this question. That was not enough for the FDA. We believe Titan will be required to conduct additional efficacy studies with Probuphine to provide an adequate response and satisfy the FDA's request. We believe generating the data to address issue 1 and 2 could take as much as $10 million and 12 to 18 months.

Issue – 3: Human factors testing of the training associated with Probuphine's insertion and removal

Of all the issues outlined in the CRL, this is the most surprising to us. During the FDA's Psychopharmacologic Drugs Advisory Committee meeting on March 21, 2013, some of the panel members voiced concerns on the ability of psychiatrists and addiction medicine physicians being able to insert and remove the Probuphine implant without significant training. IMS Health data from January 2003 to December 2012 shows that 70% of all Suboxone (sublingual buprenorphine HCl / naloxone) prescriptions (some 40+ million prescriptions) were written by general practice / family medicine doctors, doctors of osteopathy, psychiatrists, and internal medicine specialists. However, the FDA presented data noting that primarily only surgeons and OB/GYNs have significant experience with rod insertion and/or removal.

A major concern during the panel was the potential that an addiction medicine specialist would out-source the implantation and removal of Probuphine to a surgeon. Panel members noted two potential issues here: The first is the lack of reimbursement and economics associated with such a simple procedure, meaning that surgeons are not going to take the time to come down to an opioid treatment center just to do a quick implant or removal of Probuphine; and the second issue, even if a surgeon did decide to do the procedure for a psychiatrist or addiction medicinal specialist that surgeon would not be DATA-2000 compliant. The Drug Addiction Treatment Act of 2000 allows for a waiver from the registration requirements of the Controlled Substance Act (CSA) to prescribe and dispense opioid medications in Schedule III, IV, and V for the treatment of opioid addiction, outside of an opioid treatment program, provided such medications are approved by the FDA. A non-DATA-2000 physician implanting Probuphine creates issues for the FDA and the CSA.

Interestingly enough, in Titan's two phase 3 studies (PRO-805 and PRO-806) and the two open-label extension studies (PRO-807 and PRO-811), the most common physician use was a family medicine (29%), followed by OB/GYNs (24%), and anesthesiologists, surgeons, and psychiatrists (12% each). Despite this high use of so called "physicians without significant rod insertion and/or removal", the procedure was a non-issue once Titan re-vamped the training procedure after PRO-805 and before PRO-806. Below is a slide from the FDA's Advisory Committee meeting showing 100% success on first-attempt removal for PRO-806 after the revised training and insertion / removal improvements Titan made following PRO-805.

IM-17

Study 805 & 806:
Subjects Requiring Second Attempt at Removal by Specialty of Initial Physician

	Study 805		Study 806	
	Probuphine (N=96)	Placebo (N=51)	Probuphine (N=99)	Placebo (N=48)
All specialties	n (%)	n (%)	n (%)	n (%)
Removed on first attempt	85 (88.5)	47 (92.2)	99 (100.0)	48 (100.0)
Not removed on first attempt	11 (11.5)	4 (7.8)	0 (0.0)	0 (0.0)
Ultrasound required	6 (54.5)	3 (75.0)	0 (0.0)	0 (0.0)
Ultrasound not required	5 (45.4)	1 (25.0)	0 (0.0)	0 (0.0)

Nevertheless, the FDA has asked for some additional data on this procedure and Titan and Braeburn will push forward with a simple human factors study to address the FDA's concern. We believe this study can be conducted parallel to the new clinical studies required to address issues 1 and 2 noted above.

With respect to the commercial plans, Titan and Braeburn plan to create a Probuphine steering committee to oversee the training and roll-out program. Step-1 of the program is to train 50 Master Trainers, 20 of which have already been identified from the clinical programs. These 50 Master Trainers will then train an additional 2,000 physicians over the next 12 months. Training will take place at 20-30 regional meetings with 50-100 trainees per meeting (goal of 1 trainer per 10 trainees). If Titan and Braeburn can convince each of these 50 Mater Trainers to participate in 4 meetings over the subsequent 12 months following approval, they should have no problem meeting this goal. It remains to be seen if the planned human factors study Titan plans to conduct changes the commercial training plans. The potential exists that Titan will have far more than 50 Master Trainers by the time the NDA is re-submitted to the U.S. FDA given the need to enroll the human factors study.

Issue -4: The CRL also included recommendations regarding product labeling and the implementation of the Risk Evaluation and Mitigation Strategy (REMS).

We do not see much issue here. Titan and Braeburn will take into consideration the FDA's recommendations and revise the proposed label and REMS for Probuphine to satisfy the agency. During the Advisory Committee meeting, the FDA asked the panel members to specifically discuss and vote on this issue.

Question # 3 asked, "*Is the Risk Evaluation and Mitigation Strategy (REMS) proposed by the Applicant, which consists of restricted distribution and a training / certification program for healthcare professionals who will implant the product, adequate to address the risks of potential complications associated with the implantation procedure and abuse, misuse, and accidental overdose?* Panel members were split on this question, voting 5 YES, 4 NO, and 6 ABSTAIN.

We note the FDA had significant issues with Titan's original proposed REMS, specifically with respect to the model of care and closed distribution system. The FDA wanted to bring the entire process under the roof of one DATA-2000 compliance center as noted above.

In a DATA-2000 Office Based Opioid Treatment (OBOT) center, both the physician and designated person doing the implantation / removal must complete the REMS certification. The FDA wants the product distributed from the wholesaler to an OBOT to a REMS certified physician. The OBTP will maintain Probuphine on sight for administration instead of using a specialty pharmacy model as previously suggested by Titan.

This is something we wrote about previously after the panel meeting. We do not see this as a negative issue for Titan. In fact, it simplifies the entire process in our view. However, it seems like revising the REMS and updating the proposed label was something that just could not be accomplished in only six short weeks between the panel meeting and the PDUFA action date. We wrote in our last report, "Thus, we are not sure all can be accomplished by April 30, 2013. In fact, during the committee meeting, FDA Director, Bob Rappaport, MD, hinted at the fact that there was still significant work to be done with respect to the REMS and that the combination of a priority review and REMS presented a challenge to the agency to complete by the PDUFA date."

A delay to the approval was understandable given the revised REMS. The CRL today that includes new questions around dosing and human factors testing caught us by surprise.

Significant Changes To Financial Model

Titan plans to meet with the U.S. FDA in the next few weeks to discuss the CRL. Management believes they have demonstrated clear efficacy and safety as designed and met in its pivotal phase 3 program, which included two randomized control studies and two open-label extension studies. The issues raised in the CRL, the REMS notwithstanding, are clearly a surprise.

Titan exited 2012 (December 31, 2012) with $18.1 million in cash and investments. We believe the company burned roughly $2.5 million in the first quarter 2013, putting cash at around $15.5 million as of March 31, 2013. We note that Titan has a $2.5 million scheduled installment payment to Deerfield in early April 2013. Thus, cash as of April 30, 2013 probably stood at around $12.5 million. We model cash at June 30, 2013 to be roughly $10.0 million.

We have pushed back the launch of Probuphine from July 2013 to January 2016. We removed the $50 million milestone payment from Braeburn to Titan for approval. We have increased R&D expense in 2013, 2014, and 2015 to account for the added clinical work and the preparation in re-filing the Probuphine NDA in mid-2015. We have also added 40 million shares to our fully-diluted share count number given Titan's need for cash at some point during the second half of the year. Issuing 40 million shares at around $0.40 should raise enough money to fund operations to the new PDUFA in late 2015. We suspect that many of the existing warrants and stock options previously included in our model (with exercise prices over $2 per share) will now expire worthless.

We have revised our fair-value calculation on Titan to $0.98 per share. Our model is below:

PROJECTED FINANCIALS

Titan Pharmaceuticals, Inc.
Income Statement

Titan Pharma	2011 A	2012 A	Q1 E	Q2 E	Q3 E	Q4 E	2013 E	2014 E	2015 E
Probuphine Royalty	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**	**$0**
YOY Growth	-	-	-	-	-	-	-	-	-
Fanapt Royalty	**$3.6**	**$4.8**	**$1.1**	**$1.2**	**$1.3**	**$1.3**	**$4.9**	**$5.0**	**$2.5**
YOY Growth	*42.7%*	*32.5%*	*-10.4%*	*-11.8%*	*5.9%*	*39.2%*	*3.2%*	*2.0%*	*-50.0%*
Licensing & Grant Revenue	**$0.5**	**$2.4**	**$2.0**	**$2.0**	**$2.0**	**$2.0**	**$8.0**	**$5.0**	**$0**
Total Revenues	**$4.1**	**$7.1**	**$3.1**	**$3.2**	**$3.3**	**$3.3**	**$12.9**	**$10.0**	**$2.5**
YOY Growth	*-59.7%*	*75.0%*	-	-	-	-	*81.3%*	*-22.5%*	*-75.0%*
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	$11.2	$10.6	$2.5	$2.0	$2.5	$3.0	$10.0	$10.0	$10.0
% R&D	*275.5%*	*149.1%*	-	-	-	-	*77.5%*	*100.0%*	*400.0%*
SG&A	$3.4	$4.9	$1.3	$1.1	$1.2	$1.3	$4.9	$5.2	$5.5
% SG&A	*82.8%*	*68.5%*	-	-	-	-	*38.0%*	*52.0%*	*220.0%*
Operating Income	($10.5)	($8.4)	($0.7)	$0.1	($0.4)	($1.0)	($2.0)	($5.2)	($13.0)
Operating Margin	*-258.3%*	*-117.6%*	-	-	-	-	*-15.5%*	*-52.0%*	*-520.0%*
Total Other Income	($4.7)	($1.5)	$0.1	$0.5	$0.4	$0.4	$1.4	$1.0	$1.0
Pre-Tax Income	($15.2)	($9.9)	($0.6)	$0.6	$0.0	($0.6)	($0.6)	($4.2)	($12.0)
Taxes & Other	$0	$0	$0	$0	$0	$0	$0	$0	$0
Tax Rate	*0%*	*5%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($15.2)	($9.9)	($0.6)	$0.6	$0.0	($0.6)	($0.6)	($4.2)	($12.0)
Net Margin	*-373.7%*	*-138.7%*	-	-	-	-	*-4.7%*	*-42.0%*	*-480.0%*
Reported EPS	**($0.26)**	**($0.15)**	**($0.01)**	**$0.01**	**$0.00**	**($0.01)**	**($0.01)**	**($0.03)**	**($0.09)**
YOY Growth	*171.5%*	*-42.1%*	-	-	-	-	*-95.6%*	*412.8%*	*174.7%*
Weight Ave. Shares Out	59.3	66.5	81.8	82.0	82.5	120.0	91.6	125.0	130.0

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

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Titan Pharmaceuticals, Inc.
DCF

Titan Pharmaceuticals	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023
Royalty on Fanapt (8-10%)	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0
YoY Growth	-	-	-	-	-	-	-	-	-	-	-
Royalty on Probuphine (15-20%)	$0	$0	$0	$13.1	$22.8	$40.3	$57.0	$72.0	$72.7	$73.4	$116.5
YoY Growth	-	-	-	-	*75%*	*77%*	*41%*	*26%*	*1%*	*1%*	*59%*
Licensing & Milestones	$0	$0	$0	$20.0	$0	$0	$10.0	$10.0	$10.0	$5.0	$6.0
Revenues (in Millions)	**$0**	**$0**	**$0**	**$33.1**	**$22.8**	**$40.3**	**$67.0**	**$82.0**	**$82.7**	**$78.4**	**$122.5**
CoGS	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*	*$0*
R&D	*$10.0*	*$10.0*	*$10.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*	*$5.0*
SG&A	*$4.9*	*$5.2*	*$5.2*	*$5.2*	*$5.2*	*$5.2*	*$5.2*	*$5.2*	*$5.2*	*$5.2*	*$5.2*
Other Expenses	*$0.0*	*$0.0*	*$0.0*	*$1.5*	*$2.5*	*$4.0*	*$5.7*	*$7.2*	*$7.3*	*$7.3*	*$11.7*
EBITDA	($14.9)	($15.2)	($15.2)	$21.4	$10.1	$26.1	$51.1	$64.6	$65.2	$60.9	$100.7
Depreciation and amortization	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$0.0*	*$1.0*
EBIT	**($14.9)**	**($15.2)**	**($15.2)**	**$21.4**	**$10.1**	**$26.1**	**$51.1**	**$64.6**	**$65.2**	**$60.9**	**$99.7**
EBITDA margin	-	-	-	*64.6%*	*44.2%*	*64.7%*	*76.3%*	*78.8%*	*78.9%*	*77.6%*	*81.3%*
Cash Taxes	$0	$0	$0	$0	$0	($7.8)	($15.3)	($19.4)	($19.6)	($18.3)	($29.9)
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*	*30.0%*
Balance Sheet											
Stock Options / D&A / Other	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$5.0**	**$6.0**
Non-Cash Revenue Adjustment	**$0.9**	**$0.4**	**($0.1)**	**($0.6)**	**($1.1)**	**($1.6)**	**($2.1)**	**($2.6)**	**($2.6)**	**($2.6)**	**($2.6)**
Discounted Cash Flow											
Post-Tax Operating Cash Flow	**($9.0)**	**($9.8)**	**($10.3)**	**$25.8**	**$14.0**	**$21.7**	**$38.7**	**$47.6**	**$48.1**	**$45.0**	**$73.2**
Dividends	$0	$0	$0	$0	$0	$0	$0	$0	$0	$0	$1
Free Cash Flow	**($9.0)**	**($9.8)**	**($10.3)**	**$25.8**	**$14.0**	**$21.7**	**$38.7**	**$47.6**	**$48.1**	**$45.0**	**$72.2**

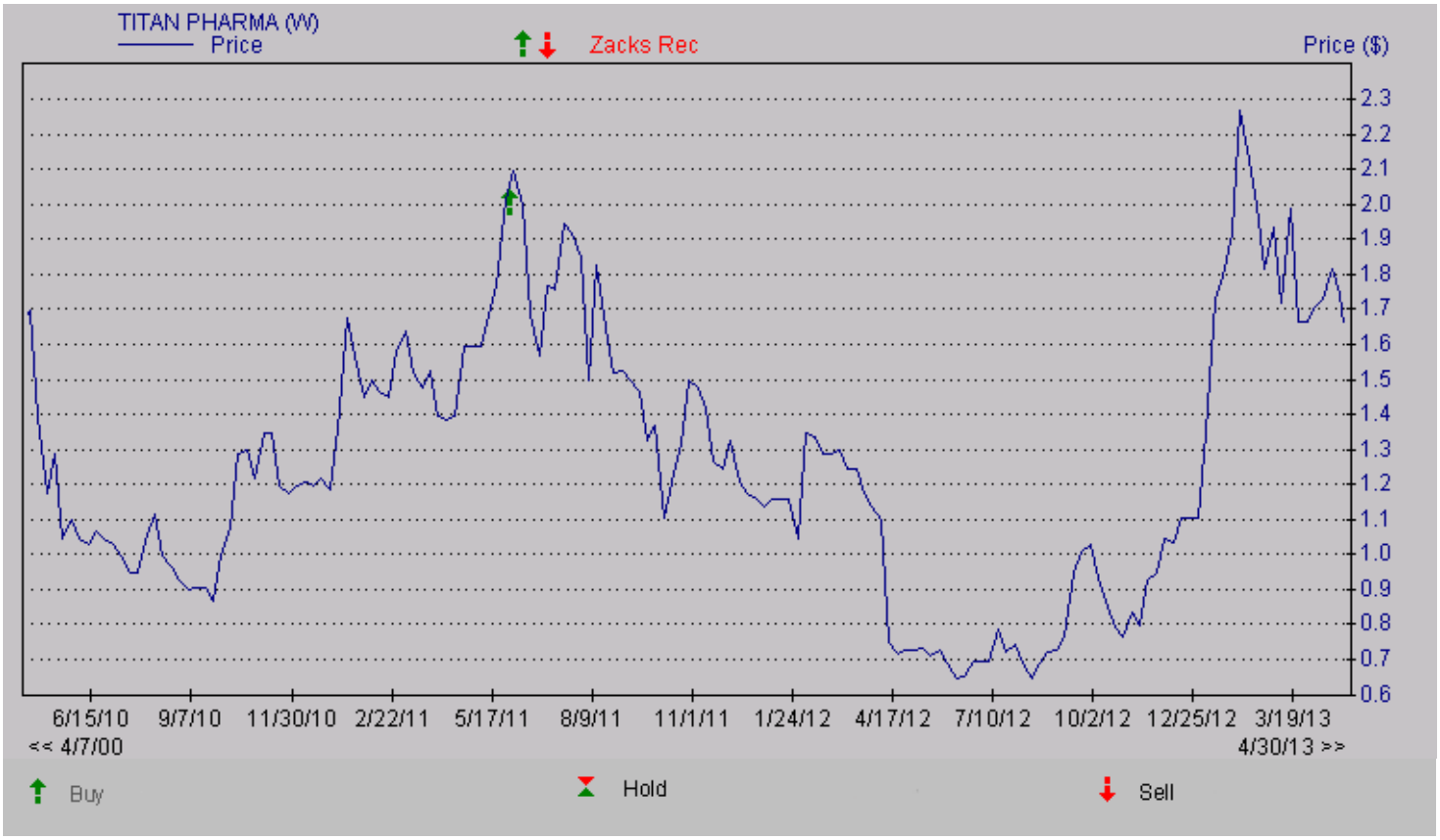
Assumptions	
Cost of Equity:	20.0%
Cost of Debt:	13.0%
Ratio D/E:	35.0%
Risk Free Rate:	2.0%
Discount Rate:	**17.5%**

Valuation	
10-Year Model:	$64.8
Terminal Growth:	0%
Terminal Value:	$69.6
CA - CL & Debt:	($9.8)
Firm Value:	**$124.6**

Price Target	
Basic Outstanding:	81.8
Options / Warrants:	5.8
Dilution:	40.0
Fully Diluted:	127.6
Target Price:	**$0.98**

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

HISTORICAL RECOMMENDATIONS



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