Zacks Small-Cap Research

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EpiCept Corp (EPCT-NASDAQ)

EPCT: looking for a strategic partner---Neutral

Current Recommendation	**Neutral**
Prior Recommendation	Outperform
Date of Last Change	05/09/2012
Current Price (05/08/12)	$0.21
12-Month Target Price	**$1.00**

OUTLOOK

EpiCept is a commercial stage specialty pharmaceutical company targeting cancer and pain markets. The Company's lead cancer candidate Ceplene has been already approved in EU and Israel for the remission maintenance of AML and a pivotal trial is approved in the US. Another important candidate is AmiKet for peripheral neuropathy, which is approved for Phase III trial. The Company has engaged SunTrust Robinson Humphrey to assist in exploring strategic alternatives to maximize its shareholder value, which include possible sale of the Company.

We are Neutral at this point of time on EpiCept shares.

SUMMARY DATA

52-Week High	**$0.69**
52-Week Low	**$0.20**
One-Year Return (%)	**-67.14**
Beta	**1.40**
Average Daily Volume (sh)	**49,321**
Shares Outstanding (mil)	**71**
Market Capitalization ($mil)	**$14**
Short Interest Ratio (days)	**6.28**
Institutional Ownership (%)	**5**
Insider Ownership (%)	**4**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**-18.2**
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	**N/A**

Risk Level	**High,**
Type of Stock	**N/A**
Industry	**Med-Drugs**
Zacks Rank in Industry	**N/A**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	0.24 A	0.22 A	0.28 A	0.21 A	0.94 A
2012	0.20 E	0.22 E	0.24 E	0.27 E	0.93 E
2013					3.00 E
2014					5.50 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2011	-$0.04 A	-$0.06 A	-$0.07 A	-$0.05 A	-$0.22 A
2012	-$0.04 E	-$0.05 E	-$0.05 E	-$0.05 E	-$0.19 E
2013					-$0.24 E
2014					-$0.27 E

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

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WHAT'S NEW

EpiCept Reports 2012 First Quarter Results

On May 9, 2012, EpiCept (EPCT) reported operating and financial results for the three months ended March 31, 2012.

Total revenue was $0.2 million during each of the first quarters of 2012 and 2011. Revenue consisted primarily of the recognition of license fee payments previously received from the Company's partners. Sales of Ceplene continued to be immaterial.

SG&A expense was $1.4 million in each of the first quarters of 2012 and 2011. The Company expects general and administrative expenses to remain at approximately current levels over the next few quarters, which should result in an approximate 20% reduction in SG&A expense by year-end 2012 when compared with 2011.

R&D expense in the first quarter of 2012 was $1.3 million, a 24% decline compared to $1.7 million in the first quarter of 2011. The decrease was primarily attributable to lower regulatory fees for Ceplene. The Company's clinical and regulatory efforts in the first quarter of 2012 were focused on its open-label trial of Ceplene® that is intended to meet its post-approval requirements with the EMA, the Fast Track application to the FDA and its meeting with the EMA regarding the Phase III development of AmiKet™ for the EU. The Company expects R&D expense to trend lower over the next few quarters as a result of a reduction in staff and reduced clinical and regulatory activity.

Net loss for the first quarter of 2012 was $4.7 million, or $0.06 per share, compared with a net loss of $2.5 million, or $0.04 per share, for the first quarter of 2011. The net loss for the first quarter of 2012 includes $1.2 million of deemed dividends on convertible preferred stock.

EpiCept had approximately $5.1 million in cash and cash equivalents as of March 31, 2012. In April 2012 the Company received approximately $1.0 million cash, net of $0.1 million in transaction costs, from the issuance of 1,065 shares of the Company's Series B 0% Convertible Preferred Stock, at a price of $1,000 per share, and warrants to purchase 3.1 million shares of the Company's Common Stock. The Shares of Series B Preferred Stock are convertible into an aggregate of 6.3 million shares of the Company's Common Stock. The Company believes that its current cash is sufficient to fund operations into the third quarter of 2012.

Clear Regulatory Pathway of AmiKet Identified

EpiCept's focus has shifted to AmiKet from Ceplene recently and the Company's success will be dependent on finding a partner for AmiKet or a buyer for the Company.

On January 24, 2012, EpiCept Corporation (EPCT) received further encouraging guidance for the **Phase III** clinical and nonclinical development and subsequent New Drug Application (NDA) filing of **AmiKet**™ in the treatment of chemotherapy- induced peripheral neuropathy (CIPN) based on the issuance of the final minutes of the Company's meeting with the FDA in December 2011.

AmiKet™ is a prescription, topical analgesic cream containing amitriptyline 4% and ketamine 2% designed to provide relief from neuropathic pain, which affects more than 15 million people in the U.S. alone. In the first half of 2011, EpiCept announced positive results from a National Cancer Institute-sponsored study evaluating the efficacy and safety of AmiKet™ in chemotherapy-induced peripheral neuropathy (**CIPN**), a painful condition that frequently occurs following systemic chemotherapy and that may interrupt, delay or even prevent completion of potentially curative chemotherapy regimens. A safe

and effective therapeutic option for neuropathic pain associated with CIPN would address a significant unmet medical need.

In addition to the positive outcome previously reported for AmiKet™ in CIPN, EpiCept has reported statistically significant positive results in the treatment of pain from post-herpetic neuralgia in several Phase II studies, the non-inferiority of AmiKet™ compared with gabapentin in another placebo controlled study, and a positive trend in the treatment of pain in a diabetic neuropathy Phase II study.

In the final meeting minutes recently received by EpiCept, the FDA acknowledged that painful symptoms due to CIPN represent a significant unmet medical need and encouraged EpiCept to apply for Fast Track designation. Further, the FDA waived several expensive and time consuming non-clinical toxicology studies, and indicated that a single four-arm factorial trial might suffice for regulatory approval if combined with other pivotal data in another neuropathy such as diabetic peripheral neuropathy.

The key element of the proposed Phase III clinical program is a 12-week, four-arm, factorial designed trial in CIPN that would seek to demonstrate AmiKet's superiority compared with placebo and with each of the component drugs of AmiKet™, amitriptyline and ketamine. EpiCept intends to submit the protocol for this trial to the FDA via a Special Protocol Assessment (SPA). An additional two-arm efficacy study in another painful peripheral neuropathy may be performed as an alternative strategy to a second factorial-designed trial for the NDA filing, which could potentially lead to a broader label in the treatment of peripheral neuropathic pain.

The meeting minutes included a summary of the nonclinical program requirements to file an NDA, which notably included only a single dermal carcinogenicity study. The dermal photo-irritation/toxicity assessment may be waived, provided dermal photo-irritation is assessed in the clinical program. A COMET assay (Single Cell Gel Electrophoresis to detect DNA damage) study is required prior to initiation of the long-term open label clinical safety study.

We think the minutes from the FDA meeting are very positive. The FDA's requirements for the clinical and nonclinical programs to support an AmiKet™ NDA filing are achievable. This is a very favorable outcome that will likely benefit AmiKet's market opportunity and time to NDA filing. Further, this will facilitate SunTrust Robinson Humphrey's efforts to identify potential acquirers or strategic partners to advance AmiKet™ towards approval and commercialization in the United States. This program may also facilitate the filing of a marketing authorization application (MAA) for the European Union.

Amiket was granted **Fast Track Status** by the FDA in April 2012 for the treatment of CIPN. EpiCept also held a meeting with the European Medicines Agency (EMA) to review the Phase III requirements for obtaining marketing approval in the European Union (EU) during 1Q12.

A Strategic Partner is Needed to Advance AmiKet™

On January 9, EpiCept announced that it has engaged SunTrust Robinson Humphrey to assist in exploring strategic alternatives to maximize the commercial opportunity of AmiKet™. The engagement is focused on the identification and implementation of a strategy that will optimize AmiKet’s value for the Company’s stockholders, which includes the evaluation of potential transactions involving the sale of the Company.

During the fourth quarter of 2011, a U.S. market evaluation of the CIPN opportunity was completed by an independent market assessment firm engaged by EpiCept. Among the study's conclusions was that peak annual revenue for AmiKet™ treating CIPN in the U.S. alone could exceed $400 million through a specialty pharmaceutical sales force of less than 150 targeting the top six deciles of prescribing oncologists, pain specialists and neurologists. The study determined that the number of cases of malignant cancer diagnoses of breast, prostate, lung and ovarian cancers currently exceeds 3.5 million, and estimated that 90% of all prostate and ovarian cancer patients, 75% of all breast cancer patients and more than 60% of all lung cancer patients are treated with taxanes, either alone or in combination with

other chemotherapeutic drugs. Based on physician interviews, expert opinions and a review of the medical literature, the study concluded that a significant percentage of this group develops some form of CIPN.

A successful outcome of this engagement will enable the product to move forward quickly through its final stage of clinical and regulatory development. This will optimize AmiKet's value for the Company's shareholders in our view.

Other Clinical Programs Updates

The Ceplene Program:

Ceplene has been approved in the EU and Israel for administration with low-dose interleukin-2 (IL-2) for the remission maintenance and prevention of relapse of patients with Acute Myeloid Leukemia (AML) in first remission. The product has been licensed to Meda AB of Sweden to market and sell in Europe and certain Pacific Rim countries. Ceplene® is licensed to Megapharm Ltd. to market and sell in Israel.

Ceplene is currently on the list of pre-approved products for reimbursement in Germany, England, Sweden, Denmark and Italy (a temporary approval); additionally, it is available on a named-patient basis in many other countries in the EU. Reimbursement is being negotiated in France and Spain, among other countries in the EU. Meda continues to make progress in its long-term strategy to position Ceplene as the standard of care in AML relapse prevention by securing inclusion of Ceplene in clinical trials that are being conducted by key opinion leaders and by incorporating the use of Ceplene into treatment guidelines in major countries. Following Ministry of Health approval of labeling and other reimbursement matters expected this year, Megapharm Ltd. is expected to commence the commercial launch of Ceplene in Israel, until which time it is available there on a named-patient basis.

EpiCept is continuing patient enrollment for its European post-approval clinical study of Ceplene. This study is intended to measure immune activation and the eradication of detectable minimal residual disease in AML patients serving as their own controls. More than 75 patients have been enrolled to date. Biomarker data from the first 75 patients enrolled are expected to be reported later in 2012. Thirty centers across Europe are participating in this study, with sites in Sweden, Belgium, France, the U.K., Spain, Germany and Italy. The Company intends to use the data from this single-arm, open-label trial to meet its post-approval commitment and to seek a refinement of Ceplene's EU labeling. The data also are expected to have value for Meda in marketing Ceplene® to prescribing hematologists.

Crolibulin

As a vascular disruption agent, Crolibulin has demonstrated potent anti-tumor activity in both preclinical and early clinical studies. In December 2010, the NCI initiated a **Phase Ib/II** trial for Crolibulin to assess safety and efficacy in combination with cisplatin in patients with **anaplastic thyroid cancer (ATC).**

The Phase I safety portion of the combination study with cisplatin is nearing conclusion, after which the Phase II randomized efficacy proof-of-concept study is expected to commence.

Azixa

Azixa is discovered by EpiCept and licensed to **Myrexis, Inc**. as part of an exclusive, worldwide development and commercialization agreement. Azixa has received orphan drug status in the U.S. for the treatment of glioblastoma multiforme (GBM).

In June 2011, Myrexis presented **Phase II** clinical results at the American Society of Clinical Oncology (ASCO) Annual Meeting from the company's open-label study in patients with recurrent GBM, concluding that AzixaTM was active and well tolerated in patients who failed first-line therapy.

Myrexis announced in February 2012 that it has suspended company-wide operations pending the outcome of an evaluation of available strategic alternatives to enhance shareholder value that is being undertaken by its investment bank. Myrexis is initiating an alignment of resources consistent with its decision to suspend further development activities.

EpiCept is closely monitoring the developments and intends to enforce its rights as appropriate under its license agreement with Myrexis.

VALUATION AND RECOMMENDATION

We downgrade EpiCept shares from Outperform to Neutral rating on EpiCept Corp. Our new 12-month price target is $1.00 per share.

Our call is based on the change of the Company's fundamentals.

EpiCept is a specialty pharmaceutical company targeting two large and underserved markets: cancer treatment and pain management. The Company's key product candidate Ceplene has been approved in Europe and Israel for the maintenance therapy of AML. Ceplene has been commercially launched in UK, Germany and Austria and will continue to be launched in other European countries and Israel this year. However, sales continue to be immaterial in these approved markets.

We think Ceplene is almost dead in the US due to the new regulatory requirements issued by the FDA. The Company filed its protocol for a **Phase III** confirmatory clinical trial for Ceplene with the FDA in the second quarter of 2011, and a meeting with the FDA was held in September 2011 to reconcile the major protocol elements. At the meeting, the FDA indicated that as part of a registration study, the effect of Ceplene must be isolated from the effect of IL-2; therefore the FDA's preferred study design is a comparison of Ceplene/IL-2 vs. IL-2 monotherapy at the same IL-2 dosing regimen as those patients receiving Ceplene/IL-2 in combination. The FDA also indicated the need to demonstrate as the primary endpoint a significant benefit of Ceplene/IL-2 vs. IL-2 monotherapy on overall survival. At this time, **the Company is not pursuing the Phase III trial** given that IL-2 monotherapy has failed to demonstrate any significant statistical or clinical benefit in maintaining AML remission in six separate clinical trials conducted by several prominent international study groups in the past several years. Further, the significant cost to run such a trial and the time required to achieve a meaningful overall survival endpoint render its undertaking by the Company impractical at this time.

Therefore, the Company has shifted its focus to Amiket. We believe AmiKet has great potential, but a partner is needed to advance this candidate into Phase III trial and commercialization considering a huge amount of money is needed for the Phase III trial alone.

Currently, the Company shares are trading at about $0.20 per share which values the Company at about $14 million based on 71 million shares outstanding. We believe the share price will stay around $0.20 for a while until a final deal is closed for AmiKet. At that time, the Company's shares may rise to $1 dollar, which values the Company at $71 million in terms of market capitalization.

But Cash Position is still Our Chief Concern

EpiCept has a relatively weak balance sheet. Since its inception, the Company has been losing money due to lack of meaningful revenue and high costs related to R&D programs and SG&A.

With the approval of Ceplene in EU and Israel, the situation could change in the coming years in terms of revenue growth, but sales of Ceplene will still be incremental in 2012.

As of March 31, 2012, EpiCept had approximately $5.1 million in cash and cash equivalents. Current cash is only sufficient to fund operations into the third quarter of 2012. If the Company can't find a partner for AmiKet, it may need to tap the capital market very soon.

EpiCept is considering various financing opportunities to obtain additional cash resources to fund operations and clinical trials, including the sale or licensing of assets and the sale of equity securities. While the Company expects to receive cash from sales of Ceplene to Meda and royalties on the sales of Ceplene by Meda and Megapharm, such cash payments are not expected to provide meaningful funding for the Company's operations in 2012.

We remind investors, equity financing will dilute existing shareholder base, and share price will suffer.

PROJECTED INCOME STATEMENT

	2010A (Dec)	2011A (Dec)					2012E (Dec)					2013E (Dec)	2014E (Dec)	2015E (Dec)
$ in million except per share data	FYA	Q1A	Q2A	Q3A	Q4A	FYA	Q1	Q2	Q3	Q4	FYE	FYE	FYE	FYE
Product Revenue	$0.17	$0.05	$0.00	$0.03	$0.00	$0.09	$0.05	$0.07	$0.09	$0.12	$0.33	$1.50	$3.50	$7.50
R&D revenue	$0.80	$0.19	$0.22	$0.24	$0.20	$0.86	$0.19	$0.15	$0.15	$0.15	$0.64	$0.50	$0.50	$0.50
Total Revenues	**$0.97**	**$0.24**	**$0.22**	**$0.28**	**$0.21**	**$0.94**	**$0.24**	**$0.22**	**$0.24**	**$0.27**	**$0.97**	**$2.00**	**$4.00**	**$8.00**
YOY Growth	*133.3%*	*42.5%*	*-10.8%*	*7.0%*	*-28.9%*	*-2.3%*	*1.3%*	*-1.8%*	*-12.7%*	*30.4%*	*308.0%*	*792.9%*	*1354.5%*	*3764.7%*
CoGS	0.97	0.09	0.27	0.05	0.28	0.69	0.00	0.05	0.05	0.05	0.15	1.00	2.00	3.60
Gross Income	**($0.00)**	**$0.15**	**($0.05)**	**$0.22**	**($0.07)**	**$0.25**	**$0.24**	**$0.17**	**$0.19**	**$0.22**	**$0.82**	**$1.00**	**$2.00**	**$4.40**
Gross Margin	*-0.2%*	*62.2%*	*-20.5%*	*81.5%*	*-35.7%*	*26.7%*	*99.6%*	*77.3%*	*79.2%*	*81.5%*	*84.4%*	*50.0%*	*50.0%*	*55.0%*
SG&A	$7.25	$1.39	$2.04	$1.98	$1.04	$6.45	$1.43	$1.43	$1.45	$1.46	$5.77	$8.50	$10.00	$12.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$8.13	$1.68	$1.99	$2.62	$1.56	$7.85	$1.30	$1.40	$1.50	$2.00	$6.20	$10.00	$15.00	$12.00
% R&D	-	-	-	-	-	-					-	-	-	-
Other	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00	$0.00
% Other	-	-	-	-	-	-					-	-	-	-
Operating Income	**($15.4)**	**($2.9)**	**($4.1)**	**($4.4)**	**($2.7)**	**($14.1)**	**($2.5)**	**($2.7)**	**($2.8)**	**($3.2)**	**($11.1)**	**($17.5)**	**($23.0)**	**($19.6)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.2)	$0.5	($0.3)	($1.0)	($0.8)	($1.6)	($2.2)	($0.2)	($0.2)	($0.2)	($2.8)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($15.5)**	**($2.5)**	**($4.3)**	**($5.4)**	**($3.5)**	**($15.7)**	**($4.7)**	**($2.9)**	**($3.0)**	**($3.4)**	**($14.0)**	**($18.3)**	**($24.0)**	**($20.6)**
Income taxes(benefit)	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Reported Net Income	**($15.5)**	**($2.5)**	**($4.3)**	**($5.4)**	**($3.5)**	**($15.7)**	**($4.7)**	**($2.9)**	**($3.0)**	**($3.4)**	**($14.0)**	**($18.3)**	**($24.0)**	**($20.6)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*47.8*	*60.1*	*71.0*	*71.0*	*71.0*	*68.3*	*77.1*	*80.0*	*81.5*	*82.5*	*80.3*	*85.0*	*90.0*	*95.0*
Reported EPS	**($0.32)**	**($0.04)**	**($0.06)**	**($0.08)**	**($0.05)**	**($0.23)**	**($0.06)**	**($0.04)**	**($0.04)**	**($0.04)**	**($0.17)**	**($0.22)**	**($0.27)**	**($0.22)**
YOY Growth	-					-	-	-	-	-	-	-	-	-
One time charge	*$0.00*	*$0.00*	*$0.00*	*$0.62*	*$0.00*	*$0.62*	*$0.94*	*$0.00*	*$0.00*	*$0.00*	*$0.94*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($15.5)**	**($2.5)**	**($4.3)**	**($4.8)**	**($3.5)**	**($15.0)**	**($3.8)**	**($2.9)**	**($3.0)**	**($3.4)**	**($13.0)**	**($18.3)**	**($24.0)**	**($20.6)**
Non GAAP EPS	**($0.32)**	**($0.04)**	**($0.06)**	**($0.07)**	**($0.05)**	**($0.22)**	**($0.05)**	**($0.04)**	**($0.04)**	**($0.04)**	**($0.16)**	**($0.22)**	**($0.27)**	**($0.22)**

Source: Company filings and Zacks Investment Research estimates

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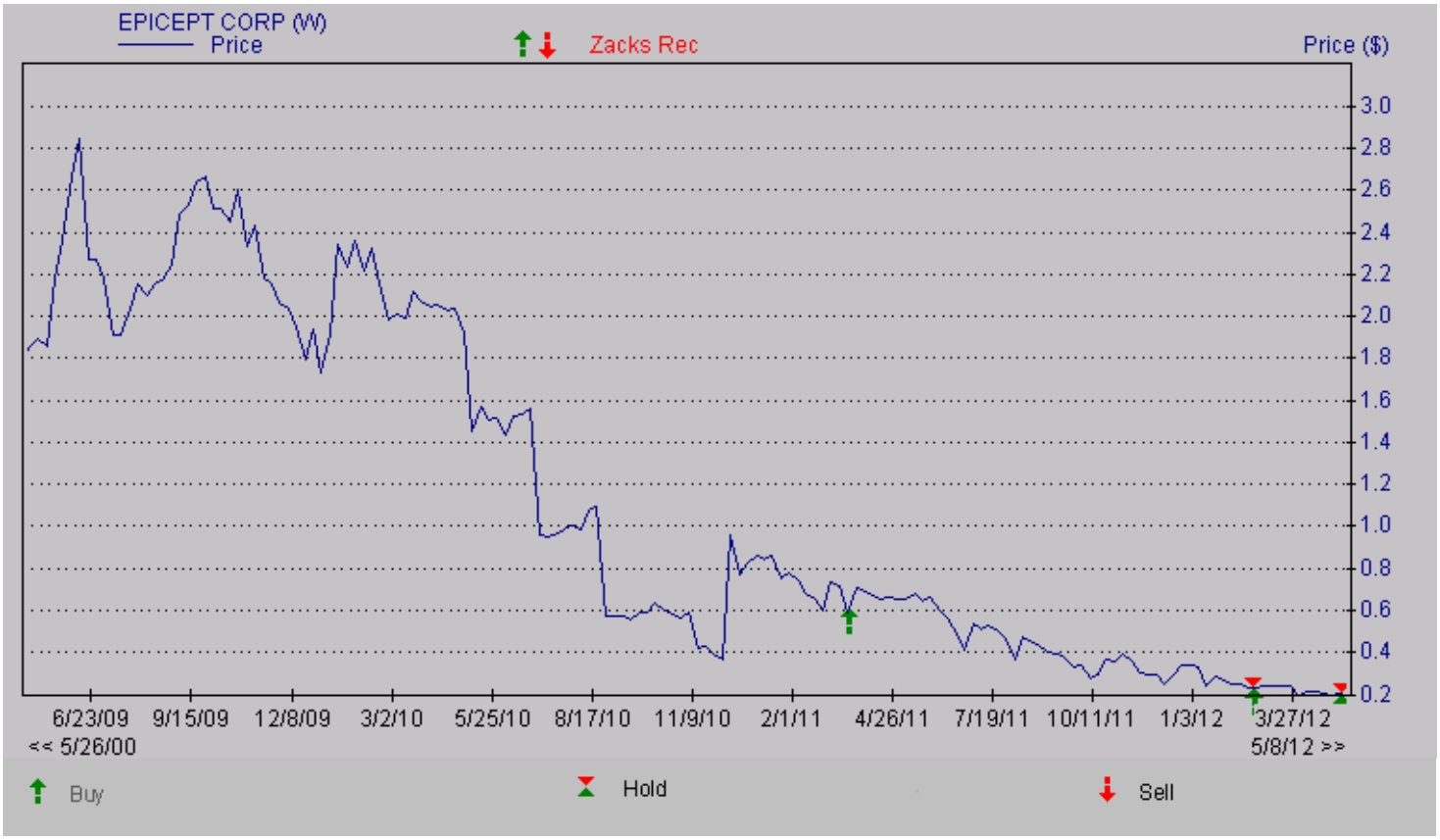
HISTORICAL ZACKS RECOMMENDATIONS



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