Zacks Small-Cap Research

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EpiCept Corp (EPCT-NASDAQ)

EPCT: Pipeline with late stage candidates targets two large markets of cancer treatment and pain management----initiating with an Outperform rating

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	03/21/2011
Current Price (03/21/11)	$0.66
Target Price	**$2.50**

OUTLOOK

EpiCept is a commercial stage specialty pharmaceutical company targeting large 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 planned in the US. The Company's other candidates include NP-1 for peripheral neuropathy, Azixa and Crolibulin for cancers which are all in Phase II trials. We are optimistic about EpiCept's prospect. Current valuation is low and we see a great potential for appreciation in share price as the Company continues to advance its pipeline and boosts its balance sheet.

SUMMARY DATA

52-Week High	**$2.12**
52-Week Low	**$0.33**
One-Year Return (%)	**-63.47**
Beta	**1.73**
Average Daily Volume (sh)	**283,176**
Shares Outstanding (mil)	**64**
Market Capitalization ($mil)	**$47**
Short Interest Ratio (days)	**2.53**
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	**77 of 87**

ZACKS ESTIMATES

Revenue
(in millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	0.17 A	0.25 A	0.26 A	0.29 A	0.97 A
2011	0.22 E	0.24 E	0.26 E	0.28 E	1.00 E
2012					2.25 E
2013					4.00 E

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

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2010	-$0.10 A	-$0.11 A	-$0.06 A	-$0.06 A	-$0.32 A
2011	-$0.05 E	-$0.07 E	-$0.07 E	-$0.09 E	-$0.29 E
2012					-$0.26 E
2013					-$0.25 E

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

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KEY POINTS

- We are initiating coverage of EpiCept (EPCT) with an Outperform rating. Our price target is $2.50 per share. Our call is based on the strong fundamentals of the Company.

- EpiCept is a commercial stage specialty pharmaceutical company targeting two large markets of cancer treatment and pain management.

- The Company's lead cancer product candidate Ceplene has been approved in the EU and Israel for the remission maintenance of AML in combination with IL-2. Commercial launch of Ceplene has begun in UK, Germany and Austria and will continue in other countries. In the US, a pivotal Phase III trial is planned late this year.

- Ceplene remains the Company's key value driver both in the near term and in the long run. Sales from the compound will make meaningful contribution to the Company's top line growth from 2012 onwards, especially when it's approved in the US in 2015.

- Another key value driver for EpiCept is NP-1 for the treatment of peripheral neuropathy, a large, underserved market. Positive results from multiple Phase II trials support pivotal Phase III trials. The Company has been seeking potential partners for this program and a deal could be announced later this year.

- In addition to Ceplene and NP-1, two other cancer candidates Azixa and Crolibulin are under Phase II clinical trials for glioblastoma and anaplastic thyroid cancer, respectively.

- EpiCept's shares are undervalued in our view. We see a favorable reward/risk profile for the Company at this point. Therefore, we have an Outperform rating for the Company. Risks associated with our call are weak balance sheet and regulatory uncertainties for its major drug candidates.

OVERVIEW

EpiCept is a specialty pharmaceutical company focused on the development and commercialization of pharmaceutical products for the treatment of **cancer** and **pain**. The Company's strategy is to focus its development efforts on innovative cancer therapies and topically delivered analgesics targeting peripheral nerve receptors.

The Company's lead product is **Ceplene**, which is used concomitantly with low dose interleukin-2 (IL-2) for remission maintenance therapy of acute myeloid leukemia (AML) for adult patients who are in their first complete remission. Ceplene has been approved in the **European Union** (EU) and **Israel**. The product has been licensed to Meda AB of Sweden to market and sell in Europe and certain Pacific Rim countries, and to MegaPharm Ltd. to market and sell in Israel. Meda AB has launched Ceplene in UK, Germany and Austria and will continue in other European countries.

In the US, EpiCept plans to conduct a new confirmatory clinical trial to demonstrate Ceplene's activity in conjunction with low-dose IL-2 as remission maintenance therapy for AML patients in first complete remission with overall survival as the primary endpoint. The Company expects to begin the trial in the second half of 2011.

In Canada, EpiCept is seeking data protection for Ceplene. This has been denied by a federal court in Canada. The Company expects to appeal the court's decision and has withdrawn its New Drug

Submission until the appeals process is completed. The Company retains the right to re-file the application at any time over the next five years without prejudice.

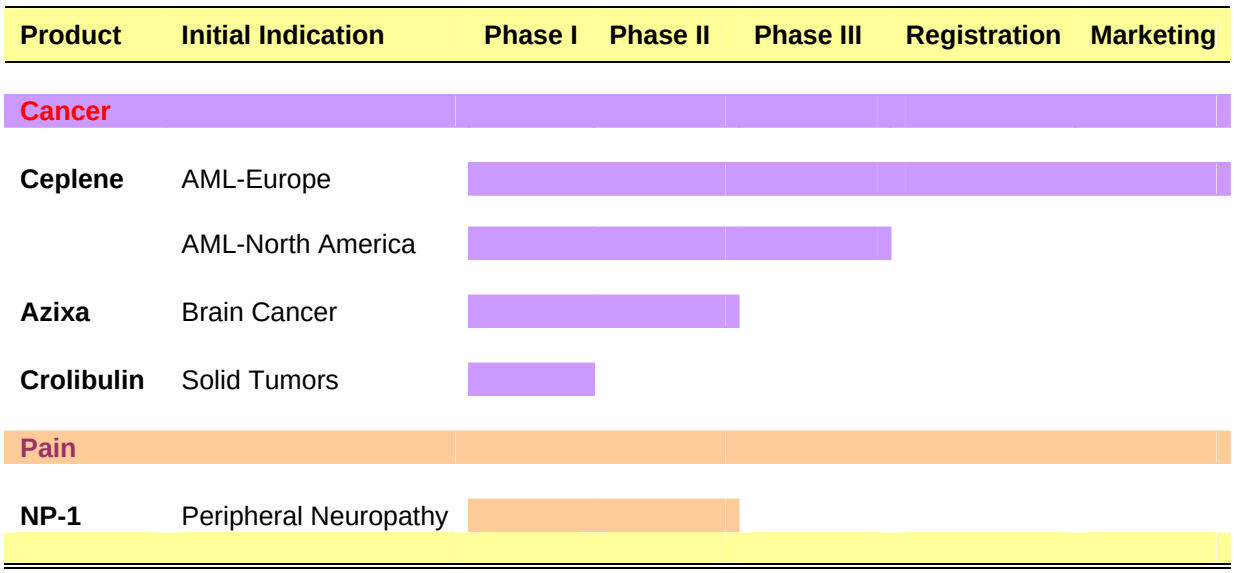
The Company's other oncology compounds include **crolibulin**, a novel small molecule vascular disruption agent (VDA), and apoptosis inducer for the treatment of patients with solid tumors and lymphomas. In December 2010, the NCI initiated a **Phase Ib/II** trial for crolibulin to assess safety and efficacy in combination with cisplatin in patients with anaplastic thyroid cancer (ATC). Trial enrollment has commenced and data from the Ib portion of this trial could be available as early as in late 2011.

Another cancer candidate is **Azixa**, an apoptosis inducer with VDA activity licensed by the Company to Myrexis, Inc. (formerly Myriad Pharmaceuticals, Inc.), as part of an exclusive, worldwide development and commercialization agreement. Azixa is currently in **Phase II** clinical trials for the treatment of glioblastoma.

In the area of pain management, the Company's pain product candidate, **EpiCept NP-1 (NP-1)**, is a prescription topical analgesic cream designed to provide effective long-term relief of pain associated with peripheral neuropathies. EpiCept has completed five double blind placebo controlled **phase II studies** of NP-1 for post-herpetic neuralgia (PHN), diabetic peripheral neuropathy (DPN) and chemotherapy induced peripheral neuropathy (CIPN), respectively. All Phase II studies support the advancement of NP-1 into a registration-sized trial. EpiCept intends to partner NP-1 prior to the commencement of the Phase III program in order to share the costs and development risk, and ultimately to have that partner market the product globally upon approval.

EpiCept is based in Tarrytown NY. The Company has a 100%-owned subsidiary in Germany, **EpiCept GmbH** that performs certain research and development activities.

Figure 1: Development Pipeline



Source: Company website and Zacks Investment Research

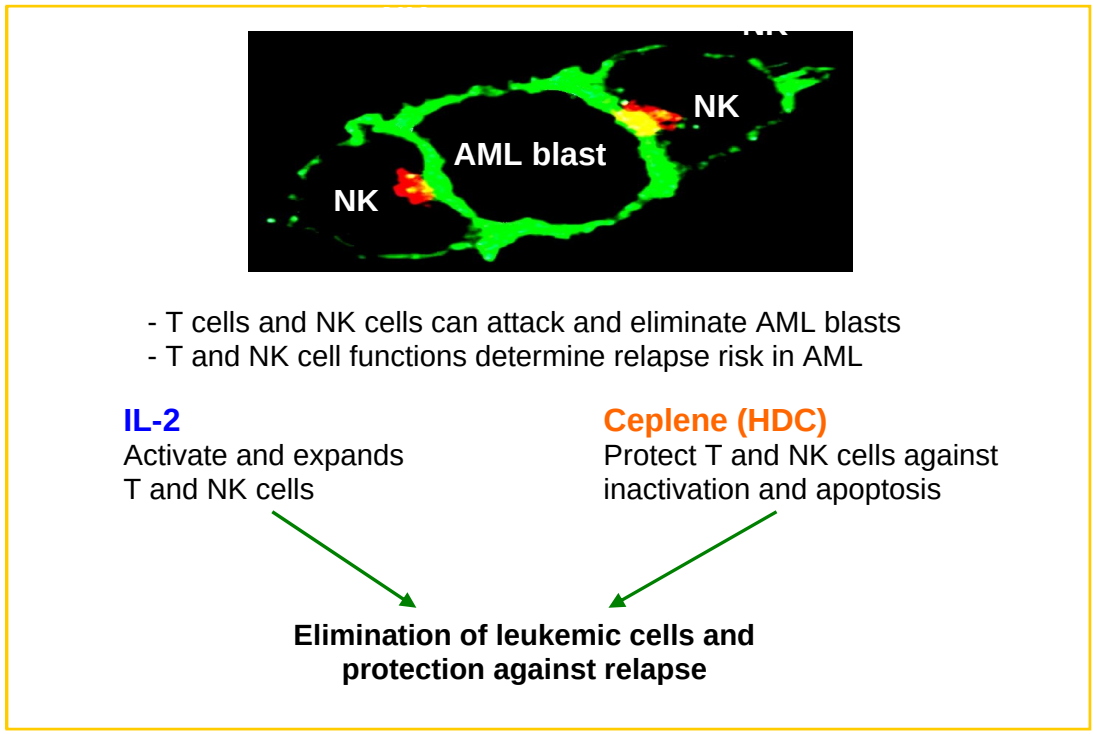
INVESTMENT THESES

Ceplene, the Key Value Driver

EpiCept's lead product candidate is **Ceplene** which belongs to a group of medicines called immunomodulator. These medicines help the body's immune system fight diseases like cancer by improving the immune system's natural role in fighting disease. The active substance in Ceplene is **histamine dihydrochloride (HDC)**. It is identical to a naturally occurring substance in the body. Ceplene is used together with low doses of **interleukin-2 (IL-2),** another medicine which helps the immune system to fight diseases like cancer.

Ceplene is developed for the **maintenance of remission** in adult patients with **acute myeloid leukaemia (AML)** in first remission concomitantly treated with IL-2. Ceplene/IL-2 is an immunotherapy which aims to induce immune-mediated destruction of residual myeloid leukaemic cells and thereby to prevent relapse of leukaemia. The role of Ceplene is to protect lymphocytes, in particular NK cells and T cells, which are responsible for the immune mediated destruction of residual leukaemic cells. The role of IL-2 is to promote the functions of NK cells and T cells by activating the anti-leukaemic properties of these cells and by expanding these cell populations by inducing cell cycle proliferation. Ceplene improves the anti-leukaemic function of lymphocytes in AML by inhibition of reactive oxygen species (ROS or oxygen free radicals), which are synthesized by monocytes/macrophages and granulocytes. ROS are known to limit the anti-leukaemic effects of lymphocyte activators such as IL-2, by triggering dysfunction and death by apoptosis in NK cells and T cells. Ceplene inhibits nicotinamide adenine dinucleotide phosphate-oxidase (NADPH) which initiates the formation and release of ROS from phagocytes. By inhibiting oxidase function and reducing ROS production, Ceplene protects IL-2-activated NK cells and T cells from oxygen free radical-induced inhibition and apoptosis. The concomitant administration of Ceplene and IL-2 therefore aims to optimize the anti-leukaemic functions of NK cells and T cells.

Figure 2: the synergies between Ceplene and IL-2 for the treatment of AML



Source: Company presentation

In Europe, Ceplene was approved by the European Commission in October 2008. In January 2010 EpiCept completed an agreement with **Meda AB** of Sweden. Under the terms of the agreement, EpiCept granted Meda the right to market Ceplene in Europe and Pacific Rim countries including Japan, China, and Australia. EpiCept received a $3 million fee on signing and an additional $2 million upon the first commercial launch of Ceplene. Additional payments include a $5 million payment upon achievement of a regulatory milestone and up to $30 million in sales-based milestones that commence upon attainment of at least $50 million in annual sales. EpiCept will receive a double digit percent royalty on net sales in the covered territories and will be responsible for Ceplene's commercial supply.

Meda has commercially launched Ceplene in UK, Germany and Austria and will continue to launch the product in other European countries. Currently, Meda is concentrating on gaining patient access to Ceplene through its inclusion in clinical trials that are being conducted by key opinion leaders. Regulatory efforts include seeking reimbursement approvals in France, Spain, Italy and smaller markets in the EU, and filing for marketing approval in non-EU European and Pacific Rim countries. Reimbursement approvals are expected during 2011 and several marketing applications are expected to be submitted in 2011. Sales of Ceplene were not material in the fourth quarter of 2010 and are not expected to grow significantly until 2012.

The EU approval of Ceplene was based on two clinical studies to evaluate the use of Ceplene in the maintenance of remission in adult AML patients. **Study AML-1** was exploratory, enrolling 39 AML patients in remission to determine the dose and feasibility of Ceplene administered together with IL-2. Results of this pilot study were used to design and implement a multi-national **Phase III trial**. The randomised Phase III trial (0201) compared Ceplene+IL-2 treatment to no treatment in 261 patients in first remission (CR1) and in another 59 patients in subsequent remission after relapse (CR>1). For CR1 patients, the median duration of leukaemia-free survival increased from 291 days (9.7 months) to 450 days (15 months) after Ceplene/IL-2 versus no maintenance treatment (ITT, p=0.01. n=261). The number of CR1 patients remaining leukaemia-free for 3 years was 40% after Ceplene+IL-2 versus 26% in patients not receiving this treatment (p=0.01).

As part of receiving marketing authorization under Exceptional Circumstances for Ceplene, EpiCept is conducting a **post-approval clinical study** with Ceplene in Europe. Data is expected to be reported beginning in late 2011. Twenty eight centers across Europe are participating in this study, with sites in Sweden, Belgium, France, the U.K., Spain 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 will also have value to prescribing hematologists.

Ceplene was approved for marketing **in Israel** in the fourth quarter of 2010. Marketing is expected to commence soon by **MegaPharm**.

In November 2009, **Health Canada** screened and accepted for review a New Drug Submission (NDS) for Ceplene for remission maintenance treatment of AML in Canada. During the third quarter of 2010, the Company’s appeal of a decision by Health Canada not to provide data protection for Ceplene was denied by a federal court in Canada. Lack of data protection in Canada for an innovative drug such as Ceplene eliminates any right to sales exclusivity by the Company and enables competition to seek approval to sell generic equivalents immediately. The Company has appealed the court’s decision and withdrawn its New Drug Submission until the appeals process is completed. The Company retains the right to re-file the application at any time over the next five years without prejudice.

In the US, the Company filed a New Drug Application (NDA) with the FDA for the same indication for Ceplene in June 2010. In August 2010, the Company received a refusal to file letter from the FDA on the NDA. The FDA concluded that an additional pivotal trial assessing Ceplene’s impact using overall survival as a primary endpoint in AML patients in first complete remission needs to be conducted.

In October 2010, EpiCept reached an agreement with the FDA on a regulatory path leading to a resubmission of a NDA for Ceplene. EpiCept agreed to undertake a new **confirmatory clinical trial** to

demonstrate Ceplene's activity in conjunction with low-dose IL-2 as remission maintenance therapy for AML patients in first complete remission with overall survival as the primary endpoint without isolating the contribution of Ceplene in the regimen. The trial will be a two-arm, randomized, open-label trial that will compare the efficacy of Ceplene plus low-dose IL-2 to standard of care in this indication. EpiCept has drafted the clinical trial protocol and is now reviewing it with key opinion leaders before submitting it to the FDA. EpiCept expects to submit the protocol shortly following which the FDA, via the Special Protocol Assessment procedure, will provide guidance on specific sections of the protocol. The Company expects to begin the trial in the second half of 2011. Ceplene has been granted **orphan drug status** in the United States, which provides seven years of market exclusivity from the approval date.

We think the probability to achieve a positive result in this confirmatory trial is high. The previous Phase III trial demonstrated a statistically significant prolongation of the primary endpoint of leukemia-free survival and an advantage in increased overall survival of more than an extra year of life in all patients studied in their first complete remission. In December 2010, EpiCept released the results of a new subset analysis of 190 patients from this trial that were treated aggressively with consolidation therapy before being randomized. Within this subset of patients, a difference in overall patient survival was seen in favor of Ceplene/IL-2 versus standard of care (p= 0.07, with a median overall benefit of more than 36 months). This outcome suggests that statistically significant improved overall survival could be achieved in a well designed and adequately powered clinical trial.

Great market opportunity for Ceplene

AML is the most deadly and most common type of acute leukemia in adults. There are approximately 40,000 AML patients in the EU, with 16,000 new cases occurring each year. In the US, there are approximately 13,000 new cases of AML and 9,000 deaths caused by this cancer each year. Once diagnosed with AML, patients typically receive induction and consolidation chemotherapy, with the majority achieving complete remission. However, about 70-80% of patients who achieve first complete remission will relapse, with the median time in remission before relapse with current treatments being only 12 months. Less than 15% of relapsed patients survive long-term. With a favorable reward/risk profile, Ceplene/IL-2 provides physicians a useful tool to control and maintain remission in AML patients.

Ceplene represents a value driver for EpiCept both in the near term and in the long run. Ceplene plus IL-2 is the first and only therapeutic regime to prevent relapse and prolong leukemia free survival (LFS) in AML patients in remission. So far, there is no competing therapy in late stage clinical development. Therefore, market opportunity is significant for Ceplene. Ceplene has been designated orphan drug status in both the US and the EU which provides 7 years' marketing exclusivity in the US and 10 years in the EU. With its approval in Europe and Israel, the Company has transitioned from a pure development stage company to a commercial stage company. As commercial launch begins to roll out in individual European countries and Israel, the Company's top line will be significantly boosted in the coming years from 2012 onwards.

NP-1: Targets Large Peripheral Neuropathy Market

Another key value driver for EpiCept is its late stage drug candidate **EpiCept NP-1** (NP-1) for the treatment of **peripheral neuropathy (PN).**

NP-1 is ready for a pivotal Phase III trial

NP-1 is a prescription topical analgesic cream containing two FDA-approved drugs, amitriptyline (a widely-used antidepressant) and ketamine (an NMDA antagonist that is used as an anesthetic). NP-1 utilizes a proprietary formulation for administration directly on the skin's surface at or near the site of the pain, targeting pain that is influenced, or mediated, by nerve receptors located just beneath the skin's surface. NP-1 is designed to provide effective long-term relief of pain associated with various **peripheral neuropathies (PN).** EpiCept has completed **five Phase II** clinical trials for NP-1 including the following recent three Phase II trials.

In early February 2011, the Company reported positive results from a **Phase IIb** trial evaluating the efficacy and safety of NP-1 in chemotherapy-induced peripheral neuropathy (CIPN). The multi-center, double-blind, randomized, placebo-controlled study was conducted by the National Cancer Institute (NCI)-funded Community Clinical Oncology Program. A total of 461 cancer survivors suffering from painful CIPN were enrolled in the six-week study. The results of the trial in the intent to treat (ITT) population demonstrated that the change in average daily neuropathy intensity scores in the NP-1 group achieved a statistically significant reduction in CIPN intensity versus placebo ($p<0.001$), which was the trial's primary endpoint. Additionally, a pre-specified subgroup of the ITT population, those patients who previously received taxane chemotherapy, also showed a statistically significant reduction in average daily neuropathy intensity scores ($p=0.034$). This subgroup constituted more than 50% of the ITT population. Secondary efficacy endpoints confirmed the superiority of NP-1 vs. placebo. Furthermore, the safety profile of NP-1 was comparable to placebo.

In January 2009, the Company reported positive results from a **Phase IIb** clinical trial of NP-1 in patients suffering from **post-herpetic neuralgia** (PHN), compared to gabapentin and placebo. The trial was a randomized, double blind, placebo controlled non-inferiority trial. The trial enrolled 360 patients with the change in pain intensity as the first primary endpoint. The data demonstrated that NP-1 achieved statistically significant superior efficacy compared with placebo ($p=0.026$). An additional primary endpoint, to demonstrate that NP-1 was not inferior to gabapentin in reducing pain, was also met. A key secondary endpoint measured in the trial from a responder analysis indicated that 63% of patients in the NP-1 treatment arm achieved a reduction in pain scores of at least 30%, significantly higher than that of patients in the placebo arm ($p=0.033$). Top-line data results further indicated that NP-1 achieved a superior safety profile when compared with gabapentin, especially with regard to dizziness and somnolence. In January 2010, NP-1 received orphan drug protection for the treatment of PHN.

In February 2008, the Company reported encouraging results from a Phase II clinical study of NP-1 in patients suffering from **diabetic peripheral neuropathy** (DPN). The trial was a double blind, placebo-controlled study of NP-1 in 215 DPN patients who completed the trial. The data demonstrated that the primary endpoint, the difference in changes in pain intensity between NP-1 and placebo over the four week duration of the trial, nearly reached statistical significance ($p=0.0715$) in this Phase II study. Key secondary endpoints measured in the trial from a responder analysis indicate that 60% of patients in the NP-1 treatment arm achieved a reduction of pain scores of at least 30% compared with 48% of patients in the placebo arm ($p=0.076$). In addition, 33% of patients in the NP-1 treatment arm achieved a reduction in pain scores of at least 50% compared with 21% of patients in the placebo arm ($p=0.078$). Although this trial did not achieve statistical significance, all pain scores measured trended in favor of the NP-1 treated patients over the placebo group, indicative of an analgesic effect in this type of peripheral neuropathic pain.

We believe the positive results from the above Phase II studies support the advancement of NP-1 to a pivotal, registration-sized trial. EpiCept's plan is to find an appropriate **partner** to advance NP-1 into **Phase III** development and commercialization. With the foundation from the Phase II results, we believe it should not be difficult for the Company to strike a lucrative deal with prospective partners and this could be closed late this year.

Market opportunity for NP-1 is considerable

Peripheral neuropathy is an abnormal condition in which the peripheral nerves are damaged. The peripheral nerves spread out from the brain and spinal cord, and peripheral neuropathy results in unusual or abnormal sensations of the extremities, especially the feet. Peripheral neuropathy is a common condition and can result from many disorders or treatment of disorders such as diabetes, herpes zoster and chemotherapy. It is estimated that upwards of 20 million Americans suffer from this illness, whether they know it or not, according to the Neuropathy Association. It can occur at any age, but is more common among older adults.

Apparently, PN market is an underserved market currently. PN has not received much attention. Its extent and importance have not yet been adequately recognized. It is apt to be misdiagnosed, or thought to be merely a side effect of another disease like diabetes or cancer or kidney failure. The development of new therapies has unfortunately been slow and under funded. According to WWMR Inc., the US neuropathic pain market consisted of 4.7 million patients with $2.6 billion in sales in 2008, and is expected to grow to more than 6.1 million patients, and be valued at $5.1 billion in 2018.

Even we only consider the three sub-markets NP-1 is targeting: diabetic peripheral neuropathy (DPN), post-herpetic neuropathy (PHN) and chemotherapy-induced peripheral neuropathy (CIPN), the market is huge for NP-1.

Painful DPN is common in patients with long-standing Type I and Type II diabetes. An estimated 18.2 million people have diabetes in the United States. The prevalence of neuropathy approaches 50% in those with diabetes for greater than 25 years. Specifically, the lifetime incidence of DPN is 11.6% and 32.1% for Type I and II diabetes, respectively. Various drugs are currently used in the treatment of DPN. These include tricyclic antidepressants such as amitriptyline; anticonvulsants such as gabapentin; serotonin and norepinephrine re-uptake inhibitors (e.g., duloxetine), and opioids (e.g., oxycodone). Unfortunately, the use of these drugs is often limited by the extent of the pain relief provided and the occurrence of significant central nervous system side effects such as dizziness, somnolence, and confusion.

PHN is one type of peripheral neuropathic pain associated with herpes zoster (shingles). PHN affects over 100,000 people in the United States each year. PHN causes pain on and around the area of skin that was affected by the shingles rash. Most people with PHN describe their pain as “mild” or “moderate.” However, the pain can be severe in some cases. PHN pain is usually a constant, burning or gnawing pain but can be an intermittent sharp or stabbing pain. Current treatments for PHN have limited effectiveness, particularly in severe cases and can cause significant adverse side effects.

Cancer pain represents a large unmet market. This condition is caused by the cancer tumor itself as well as the side effects of cancer treatments, such as chemotherapy and radiotherapy. Over 5 million patients in the United States experience cancer-related pain. This pain can be placed in three main areas: visceral, somatic and neuropathic. Visceral pain is caused by tissue damage to organs. Somatic pain refers to the skin, muscle or bone. Neuropathic pain is caused by injury to, or compression of, the structures of the peripheral and central nervous system. Chemotherapeutic agents are associated with peripheral neuropathies.

Major competitors for NP-1 are gabapentin (generic), Lyrica (Pfizer), Cymbalta (Eli Lilly), and Lidoderm (Endo). But no current therapy is effective in more than 50% of patients. Oral therapies have CNS side effects. Lidoderm patch is not convenient for many areas prone to pain.

NP-1 is an odorless, white vanishing cream that is applied twice daily and is quickly absorbed into the applied area. The topical delivery of its patented combination represents a fundamentally new approach for the treatment of pain associated with peripheral neuropathy. In addition, the topical delivery of NP-1 will significantly reduce the risk of adverse side effects and drug to drug interactions associated with the systemic delivery of the active ingredients. Clinical study results to date have demonstrated the safety of the cream for use for up to one year and a potent analgesic effect in subjects with PN. The favorable efficacy data and risk profile, combined with its convenience of use will make NP-1 a strong competitor in the PN market if approved. Furthermore, NP-1 may be used in combination with other therapies. Therefore, NP-1 should be able to command a reasonable share in the multi-billion dollar PN market.

More Opportunities for the Cancer Market

EpiCept’s pipeline targets two large markets: cancer treatment and pain management. In addition to late stage candidates Ceplene for AML and NP-1 for PN, the Company has two other oncology compounds for the treatment of cancers in clinical development.

Crolibulin targets various types of cancer

Crolibulin is a novel small molecule vascular disruption agent (VDA), and apoptosis inducer for the treatment of patients with solid tumors. Crolibulin has shown promising vascular targeting activity with potent anti-tumor activity in both pre-clinical and early clinical studies. The molecule has been shown to induce tumor cell apoptosis and selectively inhibit growth of proliferating cell lines, including multi-drug resistant cell lines. Murine models of human tumor xenografts demonstrated crolibulin inhibits growth of established tumors of a number of different cancer types. Combination therapy has also demonstrated synergistic activity in animal tumor models.

In October 2007, EpiCept completed a **Phase I** clinical trial for crolibulin. The trial successfully identified the maximum tolerated dose (MTD) of crolibulin. The MTD was below the dose which produced the expected toxicity based on preclinical studies at higher doses. Crolibulin was administered as a single agent in increasing doses to small cohorts of patients with advanced solid tumors. A total of 17 patients were enrolled in the study. The drug was tested in a variety of cancer types including melanoma, prostate, lung, breast, colon, and pancreatic cancers. In addition to determining crolibulin's MTD, the primary objective of the study was to determine the pharmacokinetic profile of the drug. In 2008, the Company enrolled an additional 16 patients into the study, lengthening the infusion period of the drug in order to increase the MTD. The studies helped characterize the pharmacodynamic effects on tumor blood flow and identified early signs of objective anti-tumor response in advanced cancer patients with well vascularized solid tumors.

In December 2010, the National Cancer Institute (NCI) has initiated a **Phase Ib/II** trial with crolibulin. The trial will assess the drug's efficacy and safety **in combination with cisplatin** in patients with **anaplastic thyroid cancer (ATC)**. The Phase II trial consists of two stages. The primary objective of the first stage is to assess the safety and tolerability of cisplatin and crolibulin given in 21-day treatment cycles. The study will assess the toxicities of crolibulin co-administered with cisplatin, evaluate dose-limiting toxicities (DLTs) and determine the MTD for the combination. The primary objective in the second stage of the trial will be to compare the combination of crolibulin and cisplatin against cisplatin alone in adult ATC patients by assessing the duration of progression-free survival (PFS). An important secondary objective is the comparison of the response rates evaluated by RECIST (Response Evaluation Criteria in Solid Tumors). Up to 70 patients are planned to be enrolled in the trial. The Phase Ib/II trial of crolibulin is based upon its early clinical data and activity observed in resistant solid tumors. Crolibulin's **dual mechanism of action** through its vascular disruptive and direct apoptotic activity may have an impact on the treatment of this disease. Trial enrollment has commenced and data from the Ib portion of this trial could be available as early as in late 2011.

ATC is an extremely aggressive cancer that has a median survival of four to five months from the time of diagnosis. Few patients survive more than one year. Treatment for most patients is generally palliative, indicating a profound unmet medical need. Crolibulin has the potential to significantly impact the lives of these patients and may further validate EpiCept's drug discovery platform.

Azixa (MPC6827) for brain cancer

As one of the molecules within the EpiCept EP90745 series of apoptosis inducer compounds intended for the treatment of cancer, **Azixa** was discovered through the Company's Anti-cancer Screening Apoptosis Platform (ASAP). In December 2003, EpiCept granted an exclusive, worldwide development and commercialization agreement for the EP90745 series (which includes Azixa) to Myrexis (formerly called Myriad Pharmaceuticals). The agreement requires that Myrexis make licensing, research and milestone payments to the Company totaling up to $27 million as well as pay an escalating mid to high single digit percentage royalty on product sales of EP90745-related products, assuming successful commercialization of any compound within the EP90745 series.

Azixa has demonstrated a broad range of anti-tumor activities against many tumor types in various animal models as well as activity against different types of multi-drug resistant cell lines. Myrexis' current focus for Azixa is on brain cancers or brain metastases due to the pharmacologic properties of Azixa in pre-clinical animal studies that indicated higher drug levels in the brain than in the blood. Azixa is currently under two Phase II clinical trials for **glioblastoma**.

In November 2010, Myrexis reported updated results from an ongoing, open-label **Phase IIa monotherapy** study of Azixa in treatment-experienced patients with glioblastoma multiforme (GBM), a primary, aggressive brain tumor. The Phase IIa trial demonstrated durable responses in patients who had failed both first- and second- line therapy. Data from a sub-group of patients with recurrent GBM who are naïve to Avastin is expected to be reported in the first half of 2011.

In December 2010, Myrexis initiated a controlled two-arm **Phase IIb** clinical study of Azixa as a front-line treatment for glioblastoma. The study will enroll up to 120 newly-diagnosed GBM patients at treatment centers in the United States and India in order to evaluate Azixa **combination therapy** as a **first-line** GBM treatment. The trial will compare standard of care in this disease with standard of care in combination with Azixa. The objective in designing the comparative Phase IIb study is to support a pivotal Phase III program.

Azixa has received orphan drug status in the United States for the treatment of glioblastoma.

Great market opportunities for Azixa

Glioblastoma multiforme (GBM), also called glioblastoma, is the most common and most aggressive type of primary brain tumor and accounts for approximately 50% to 60% of all primary brain tumors. According to National Cancer Institute (NCI), it is estimated that 22,020 people will be diagnosed with and 13,140 people will die of cancer of the brain and other nervous system in 2010 in the US. Worldwide, approximately 176,000 new cases of brain and other CNS tumors were diagnosed in the year 2000, with an estimated mortality of 128,000.

Glioblastomas are among the most aggressively malignant human neoplasms. The median survival time from the time of diagnosis without any treatment is usually less than 1 year. Despite multimodality treatment, median survival is about 14 months. The overall 5-year survival is less than 10% with the standard of care today. It is very difficult to treat glioblastoma due to several complicating factors

- The tumor cells are very resistant to conventional therapies
- The brain is susceptible to damage due to conventional therapy
- The brain has a very limited capacity to repair itself
- Many drugs cannot cross the blood-brain barrier to act on the tumor

Surgery is the first stage of treatment of glioblastoma. It is used to take a section for a pathological diagnosis, to remove some of the symptoms of a large mass pressing against the brain, to remove disease before secondary resistance to radiotherapy and chemotherapy, and to prolong survival.

After surgery, **radiotherapy** is the mainstay of treatment for glioblastoma. A pivotal clinical trial carried out in the early 1970s showed that GBM patients who received radiation had a median survival more than double those who did not receive radiation therapy. Subsequent clinical research has attempted to build on the backbone of surgery followed by radiation.

Chemotherapy (including targeted therapy) is a third method to treat glioblastoma. Although the addition of chemotherapy to radiation improves survival in many cancer types, this is not the case for glioblastoma. Most studies showed no benefit from the addition of chemotherapy to radiation for glioblastoma patients. However, currently, two chemotherapeutic agents (including one targeted therapy) approved by the FDA are frequently used for the treatment of glioblastoma in combination with radiation therapy. They are **Temodar** (temozolomide) from Merck/Schering Plough for newly diagnosed GBM and **Avastin** from Roche for recurred GBM.

A large clinical trial of 573 newly diagnosed GBM patients randomized to standard radiation versus radiation plus temozolomide chemotherapy showed that the group receiving temozolomide survived a median of 14.6 months as opposed to 12.1 months for the group receiving radiation alone. This treatment regime is currently considered standard of care for glioblastoma and has a 26% survival at two years.

The US FDA recently approved Avastin (bevacizumab) to treat patients with recurred glioblastoma (but not newly diagnosed GBM which is ICT-107's initial target) after standard therapy based on the results of 2 studies that showed Avastin reduced tumor size in some glioblastoma patients. In the first study, the efficacy of Avastin was demonstrated by an objective response rate of 25.9%. Median duration of response was 4.2 months. In the second study, the efficacy of Avastin was supported by an objective response rate of 19.6%. Median duration of response was 3.9 months.

A third chemotherapeutic agent on the market for glioblastoma is Bristol Myers Squibb's **Carmustine** injection and Eisai's **Carmustine wafer**, which are less frequently used.

Clearly, there is an unmet medical need for the treatment of glioblastoma. The glioblastoma market is a multibillion dollar business. Worldwide sales of Temodar reached $1 billion in 2009 and about $800 million in the first nine months of 2010. If Azixa ultimately reaches the market, it will become a key player in the GBM market due to its first line and second line treatment of GBM in our view. This means a lot to EpiCept since the Company will receive an escalating mid to high single digit percentage royalty on Azixa and related product sales.

INDUSTRY OUTLOOK

Our outlook for the biotech industry is positive in general.

There are a number of strong secular growth drivers that still power the biotech industry-namely, an aging population and an enormous research and development (R&D) effort to bring new, better drugs to market. People are living longer, and many have prescription pharmaceuticals to thank for it. Recent breakthroughs in oncology, neurology, and cardiology offer sizable market opportunities. Biotechnology research is finally starting to deliver. Expanded knowledge of genomics and proteomics is attracting significant attention from some of the industry's larger players. Drug companies are finding ways to reformulate and enhance current products. This is clearly a positive for the biotech industry. Demand for innovative medicines remains strong and biotechnology should deliver the next wave of pharmaceutical products to the market. This should allow the group to outperform the broader sector.

Licensing/partnership remain the lifeline of biotech industry. We expect to see continued partnership and in-licensing/out-licensing activities for biotech companies in the next few years.

We also expect further consolidation throughout the industry because we believe that current market environment in the Pharma/Biotech industry is favorable for M&A activities. The big pharmaceutical companies have long been faced with big challenges such as patent expiration for blockbusters, low research and development productivity, and generic competition. Platform technology and efficient R&D efforts in smaller biotech companies may be part of the solution to the challenges faced by big Pharma companies. As long as the challenges still exist in the pharmaceutical industry, the buyout of smaller biotech companies by big Pharma/giant biotech companies will continue to make sense.

For individual biotech companies, we think companies with one or more of the following fundamentals will be attractive.

- With approved products on the market which can generate cash for the company;

- With a strong balance sheet and low cash burn rate; huge amount of cash will be needed to provide funds for drug development before it can reach the market;

- With platform technologies with deep, diversified pipeline (from early to late stage drug candidates); platform technology can produce series drug candidates, and is usually worth more than a single drug candidate program. When a drug candidate is moving closer to market, it usually reduces development risks.

Investors should pay attention to those large profitable biotechnology stocks, as well as small-cap biotechnology stocks with promising pipelines.

VALUATION AND RECOMMENDATION

We are initiating coverage of EpiCept Corp (EPCT) with an Outperform rating. Our price target is $2.50

Our call is based on the Company's strong fundamentals. EpiCept is a specialty pharmaceutical company targeting two large and underserved markets: cancer treatment and pain management. EpiCept is already a commercial stage biopharmaceutical company. 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. In the US, a pivotal Phase III trial of Ceplene is planned to begin late this year. Compared to a pure development stage biotech company, risks for a commercial stage biotech company such as EpiCept is much lower.

In addition to Ceplene, EpiCept has two more cancer candidates: Azixa and crolibulin, both are under Phase II clinical trials.

At the pain management front, EpiCept has a late stage candidate NP-1 for the treatment of peripheral neuropathy. The Company has finished five Phase II trials and positive results support pivotal Phase III trials.

We think EpiCept is heading in the right direction and well positioned to grow dramatically in the coming years when NP-1 and Ceplene are approved in the US in 2014 and 2015 respectively. With increased top line, the Company's loss per share will be reduced each year from negative 0.32 per share in fiscal 2010 to negative 0.14 per share in fiscal 2015 according to our model.

In terms of valuation, we think EpiCept is undervalued when compared to its peers in the same industry. Currently, the Company shares are trading at about $0.7 per share which values the Company at about $45 million based on 64 million shares outstanding. This is certainly a deep discount compared to its peers. Most small biotech companies of development stage are valued from $50 to $500 million depending on how advanced the pipeline is and which indications the company is targeting. EpiCept is already a commercial stage pharmaceutical company with an approved product and several middle to late stage candidates. Also, the Company's pipeline targets two large markets of cancer treatment and pain management. Market potential is huge for the Company. Therefore, we think at this time EpiCept should be valued at about $150 million in market cap which translates into a share price of $2.50.

Catalysts over the next 12 months include:

- Ceplene commercial launches in France, Italy, Spain and other European countries
- Additional Meda regulatory filings
- Pivotal US survival trial for Ceplene to be initiated in 2H2011
- Crolibulin Phase Ib NCI combination trial results
- Further results of NP-1 chemotherapy-induced neuropathy trial

- Completion of NP-1 partnership
- Myrexis Azixa Phase II trial results

On the business development side, the Company has been exploring potential partnership opportunities for its NP-1 peripheral neuropathy program. EpiCept may announce an agreement later this year. If successful, such a partnering program not only strengths its balance sheet, but more importantly validates the Company's technology and clinical efforts.

RISKS

Cash Position is Our Chief Concern

Like most small cap biotech companies, 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 can only be meaningful from 2012 onwards.

As of December 31, 2010, EpiCept had $2.4 million in cash and cash equivalents. In February 2011, the Company received $6.6 million in net proceeds from the issuance of approximately 8.9 million shares of its common stock at $0.80 per share, and five-year warrants to purchase up to approximately 3.6 million shares of common stock at an exercise price of $0.75 per share. Current cash is sufficient to fund operations through the third quarter of 2011.

However, cash concern could be relieved by two measures. The Company has been seeking a non-equity financing transaction from accredited investors which, if completed, will support its operations well into 2012. The completion of this transaction was delayed by due diligence and other considerations, but is still ongoing.

In addition, EpiCept has been actively seeking partnership for its NP-1 program. With positive results from the Phase II clinical trials, it should not be difficult for the Company to land a lucrative partnership during 2011. This is important because such a partnership not only boosts its balance sheet, but further validates the Company's technology and clinical efforts.

Regulatory Risks still Exist

Although EpiCept's Ceplene has been approved in EU and Israel, regulatory risks still exist for the US market and in other countries. We have a high confidence in the success of the pivotal Phase III trial of Ceplene in the US, but failure can not be completely ruled out as in other pivotal trials.

The same is true for the Company's other clinical programs. The order of probability of successful marketing authorization from high to low is NP-1, Azixa, and Crolibulin in our view.

If any of the above clinical programs fails to achieve its targeted goal, the Company's share price may suffer.

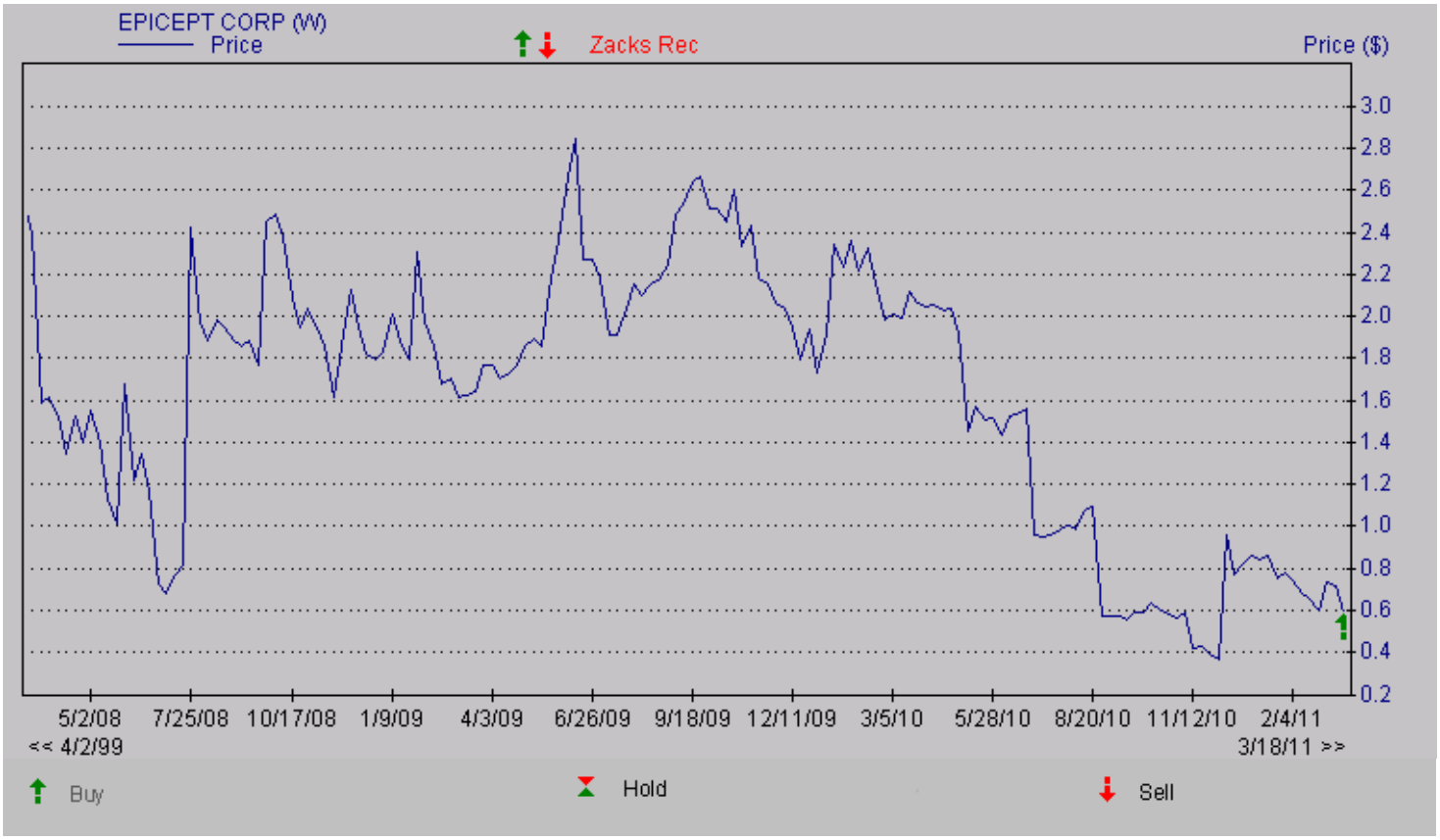
PROJECTED INCOME STATEMENT

	2010A (Dec)					2011E (Dec)					2012E (Dec)	2013E (Dec)	2014E (Dec)	2015E (Dec)
$ in million except per share data	Q1A	Q2A	Q3A	Q4A	FYA	Q1E	Q2E	Q3E	Q4E	FYE	FYE	FYE	FYE	FYE
Product Revenue	$0.00	$0.05	$0.02	$0.10	$0.17	$0.12	$0.14	$0.16	$0.18	$0.60	$1.75	$3.50	$8.00	$18.50
R&D revenue	$0.17	$0.20	$0.24	$0.19	$0.80	$0.10	$0.10	$0.10	$0.10	$0.40	$0.50	$0.50	$0.50	$0.50
Total Revenues	**$0.17**	**$0.25**	**$0.26**	**$0.29**	**$0.97**	**$0.22**	**$0.24**	**$0.26**	**$0.28**	**$1.00**	**$2.25**	**$4.00**	**$8.50**	**$19.00**
YOY Growth	*45.2%*	*175.8%*	*121.6%*	*216.3%*	*133.3%*	*33.2%*	*-4.4%*	*0.2%*	*-5.5%*	*3.0%*	*911.2%*	*1566.7%*	*3201.0%*	*6809.1%*
CoGS	0.00	0.06	0.33	0.57	0.97	0.04	0.04	0.05	0.05	0.17	0.50	1.00	2.00	3.60
Gross Income	**$0.17**	**$0.19**	**($0.08)**	**($0.28)**	**($0.00)**	**$0.19**	**$0.20**	**$0.21**	**$0.23**	**$0.83**	**$1.75**	**$3.00**	**$6.50**	**$15.40**
Gross Margin	*100.0%*	*75.3%*	*-29.6%*	*-96.9%*	*-0.2%*	*84.3%*	*83.3%*	*82.5%*	*81.8%*	*82.9%*	*77.8%*	*75.0%*	*76.5%*	*81.1%*
SG&A	$2.06	$1.72	$1.86	$1.61	$7.25	$1.75	$1.85	$1.90	$2.00	$7.50	$8.50	$9.50	$12.00	$15.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$2.04	$2.55	$2.08	$1.46	$8.13	$1.50	$2.50	$3.00	$4.50	$11.50	$12.00	$12.50	$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	**($3.9)**	**($4.1)**	**($4.0)**	**($3.4)**	**($15.4)**	**($3.1)**	**($4.2)**	**($4.7)**	**($6.3)**	**($18.2)**	**($18.8)**	**($19.0)**	**($20.5)**	**($11.6)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.6)	($0.8)	$0.84	$0.4	($0.2)	($0.2)	($0.2)	($0.2)	($0.2)	($0.8)	($0.8)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($4.5)**	**($4.9)**	**($3.2)**	**($3.0)**	**($15.5)**	**($3.3)**	**($4.4)**	**($4.9)**	**($6.5)**	**($19.0)**	**($19.6)**	**($19.8)**	**($21.5)**	**($12.6)**
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	**($4.5)**	**($4.9)**	**($3.2)**	**($3.0)**	**($15.5)**	**($3.3)**	**($4.4)**	**($4.9)**	**($6.5)**	**($19.0)**	**($19.6)**	**($19.8)**	**($21.5)**	**($12.6)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*44.2*	*44.3*	*50.4*	*52.5*	*47.8*	*63.9*	*65.0*	*67.0*	*69.0*	*66.2*	*75.0*	*80.0*	*85.0*	*90.0*
Reported EPS	**($0.10)**	**($0.11)**	**($0.06)**	**($0.06)**	**($0.32)**	**($0.05)**	**($0.07)**	**($0.07)**	**($0.09)**	**($0.29)**	**($0.26)**	**($0.25)**	**($0.25)**	**($0.14)**
YOY Growth	-	-	-	-	-					-	-	-	-	-
One time charge	$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*
Non GAAP Net Income	**($4.5)**	**($4.9)**	**($3.2)**	**($3.0)**	**($15.5)**	**($3.3)**	**($4.4)**	**($4.9)**	**($6.5)**	**($19.0)**	**($19.6)**	**($19.8)**	**($21.5)**	**($12.6)**
Non GAAP EPS	**($0.10)**	**($0.11)**	**($0.06)**	**($0.06)**	**($0.32)**	**($0.05)**	**($0.07)**	**($0.07)**	**($0.09)**	**($0.29)**	**($0.26)**	**($0.25)**	**($0.25)**	**($0.14)**

Source: Company filings and Zacks Investment Research estimates

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HISTORICAL ZACKS RECOMMENDATIONS



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