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----Outperform

Current Recommendation	**Outperform**
Prior Recommendation	N/A
Date of Last Change	03/21/2011
Current Price (01/23/12)	$0.32
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 AmiKet 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	**$0.85**
52-Week Low	**$0.25**
One-Year Return (%)	**-58.33**
Beta	**1.70**
Average Daily Volume (sh)	**138,631**
Shares Outstanding (mil)	**71**
Market Capitalization ($mil)	**$23**
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)
2010	0.17 A	0.25 A	0.26 A	0.29 A	0.97 A
2011	0.24 A	0.22 A	0.28 A	0.30 E	1.01 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	-$0.04 A	-$0.06 A	-$0.07 A	-$0.07 E	-$0.24 E
2012					-$0.26 E
2013					-$0.25 E

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

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WHAT'S NEW

Clear Regulatory Pathway of Amiket Identified

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.

New Strategy May Maximize AmiKet™ Potential

On January 9, EpiCept (EPCT) announced that it has engaged SunTrust Robinson Humphrey to assist in exploring strategic alternatives to maximize the commercial opportunity of AmiKet™. The engagement will focus on the identification and implementation of a strategy designed to optimize AmiKet's value for the Company's shareholders.

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.

EpiCept Reports Third Quarter Results

The Company recognized revenue of $0.3 million during each of the third quarters of 2011 and 2010. For each of the third quarters of 2011 and 2010, revenue consisted primarily of the recognition of license fee payments previously received from the Company's strategic alliances, which was $0.24 and $0.24 million respectively. Revenues from the sales of Ceplene to Meda and product royalties were $0.02 and $0.03 million respectively for 3Q11 and 3Q10.

SG&A expense in the third quarter of 2011 was $2.0 million, an increase of approximately 5%, or $0.1 million compared with SG&A expense of $1.9 million in the third quarter of 2010. Selling expense has been significantly reduced, and the Company expects general and administrative expenses to remain at approximately current levels over the next few quarters.

R&D expense in the third quarter of 2011 was $2.6 million, compared with $2.1 million in the third quarter of 2010, an increase of approximately 24%, or $0.5 million. The increase was primarily related to higher clinical trial costs related to the Company's post-approval trial of Ceplene. The decrease in R&D expense was primarily related to lower regulatory fees associated with the Company's NDA filing of Ceplene, partially offset by higher clinical trial expenses related to the post-approval trial of Ceplene.

GAAP net loss for the third quarter of 2011 was $5.4 million, or $0.08 per share, compared with a net loss of $3.2 million, or $0.06 per share, for the third quarter of 2010.

Non-GAAP net loss for 3Q11 was $4.8 million or $0.07 per share, compared with a non-GAAP net loss of $3.2 million or $0.06 per share for 3Q10.

As of September 30, 2011, EpiCept had cash and cash equivalents of $10.6 million.

Apparently, earnings report is a non-event for EpiCept at this time, investors are more concerned about EpiCept's clinical developments.

EpiCept Is Making Progress In Clinical Advancement and Business Development

The Amiket Program:

In the first quarter of 2011, EpiCept announced positive results from a **Phase IIb** trial evaluating the efficacy and safety of AmiKet in chemotherapy-induced neuropathic pain (CIPN).

During the second quarter of 2011, the Company commenced designing a Phase III program intended to support a New Drug Application (NDA) for AmiKet in this indication. A Phase III clinical trial protocol was prepared.

During the third quarter of 2011, EpiCept submitted its request for a meeting with the FDA to review clinical, nonclinical, regulatory and CMC plans for AmiKet in CIPN that would support FDA marketing approval. A meeting has been set for December 2011. In advance of the meeting, EpiCept has submitted to the FDA a briefing document that proposes a Phase III clinical trial protocol designed to support an NDA filing for AmiKet for the treatment of CIPN in patients who have previously received taxane-based chemotherapy. The FDA meeting is expected to provide the Company greater clarity with respect to the clinical data required for approval of AmiKet in CIPN. This guidance is expected to support ongoing partnership discussions with several interested parties.

As a reminder, AmiKet is a prescription topical analgesic cream designed to provide long-term relief from the pain of peripheral neuropathies. As no treatment has yet been approved by the FDA for CIPN, a safe and effective therapeutic option for neuropathic pain associated with CIPN represents a significant unmet medical need. Based on this unmet need and on the encouraging data from its Phase IIb trial, the Company plans to focus its development efforts for AmiKet on the treatment of neuropathic pain associated with CIPN following **taxane-based chemotherapy**.

During the third quarter of 2011, EpiCept engaged a third party to perform a CIPN U.S. market evaluation and to estimate the market opportunity for AmiKet in this indication. 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. This market evaluation will be completed in the fourth quarter of 2011.

The Ceplene Program:

Ceplene has been approved in the European Union and Israel for administration with low-dose interleukin-2 (IL-2) for the remission maintenance and prevention of relapse of patients with 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, and 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 European Union (EU). Reimbursement is being negotiated in France and Spain, among other countries in the EU. Following Ministry of Health approval of labeling and other technical matters, Megapharm Ltd. is expected to commence the commercial launch of Ceplene in Israel, until which it is available there on a named-patient basis. Sales of Ceplene were not material in the first nine months of 2011.

The Company filed its protocol for a **Phase III** confirmatory clinical trial for Ceplene with the FDA in the second quarter of 2011, and received initial written responses in June. 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 its 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. Leukemia-free survival (LFS) can be a secondary endpoint. EpiCept is working with key opinion

leaders in the preparation of a revised trial protocol, and intends to submit a revised protocol to the FDA in order to receive further guidance and approval for an SPA. This next FDA submission is anticipated to be made in the first quarter of 2012.

EpiCept is continuing patient enrollment for its European post-approval clinical study of Ceplene. Approximately 70 patients have been enrolled to date. Data from the first 75 patients enrolled are expected to be reported beginning 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 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). Trial enrollment has progressed to the third and final dosing cohort for the Phase Ib portion of this trial. The Phase II efficacy portion of the trial is anticipated to begin in the first half of 2012.

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 December 2010, Myrexis initiated a **Phase IIb** trial of Azixa in patients **newly diagnosed** with GBM. Up to 120 patients will be randomized to receive either Azixa in combination with standard of care therapy or standard of care therapy alone.

In September 2011 Myrexis suspended further development of Azixa in order to advance lead candidates from its earlier stage programs, and has announced its intentions to out-license the compound. EpiCept will protect its rights to Azixa and share in any licensing proceeds while Myrexis seeks a partner to continue development.

We think EpiCept has made excellent progress in terms of advancing its clinical programs as well as boosting its balance sheet in the past quarter. These are two key elements for a small cap biotech to achieve ultimate success. We believe EpiCept is on track to achieve its important objectives for 2012.

New Meta-Analysis Validates Ceplene's Role As A Combination Therapy With Interleukin-2 in AML Remission Maintenance

A new meta-analysis which concluded that interleukin-2 (IL-2) monotherapy is not effective as a maintenance therapy for acute myeloid leukemia (AML) patients in first complete remission was published in the July 7, 2011 edition of Blood.

The analysis appeared in an article entitled "Individual patient data meta-analysis of randomized trials evaluating IL-2 monotherapy as remission maintenance therapy in acute myeloid leukemia," and was designed to determine the efficacy of IL-2 monotherapy by combining all available individual patient data from five randomized clinical trials and summary data from a sixth trial. The combined individual patient data of 1,455 patients collected over several years showed no benefit of IL-2 compared with standard of care in terms of leukemia free survival (LFS) (p=0.74) or overall survival (OS) (p=0.39). This analysis encompasses all randomized studies examining the role of IL-2 as monotherapy in AML.

The authors highlighted the view that the efficacy of IL-2 monotherapy could be hampered by the activity of other immune cells. The findings of this meta-analysis provide further evidence of the pivotal role that **Ceplene®** plays in prolonging LFS in AML patients in first remission when used in conjunction with low-dose IL-2.

Several preclinical studies have established a role for Ceplene® (histamine dihydrochloride) to protect the viability and function of anti-leukemic lymphocytes. A **Phase III** randomized trial of AML patients in complete remission with Ceplene®/IL-2 combination therapy resulted in a significant prolongation of LFS ($p<0.01$) and a trend towards improvement in OS ($p=0.12$). The authors concluded that the suggestion that IL-2 has the potential to improve LFS and OS in AML may be valid, but for IL-2 to exert a significant clinical effect on relapse prevention in this disease, its activity may need to be protected by Ceplene®.

The conclusion of this meta-analysis further validates Ceplene's role in combination with IL-2 as effective remission maintenance therapy. EpiCept is seeking a follow-up meeting with the U.S.
Food and Drug Administration (FDA) to discuss the FDA's responses to the Company's application for a Special Protocol Assessment for Ceplene® including the FDA's initial comments on the protocol in favor of an IL-2 monotherapy arm. The meta-analysis of IL-2's lack of efficacy as a monotherapy may convince the FDA that the IL-2 monotherapy arm may not be necessary.

KEY POINTS

- We maintain our Outperform rating on EpiCept (EPCT) and reiterate our twelve month price target of $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 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 AmiKet 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 this year.

- In addition to Ceplene and Amiket, 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.

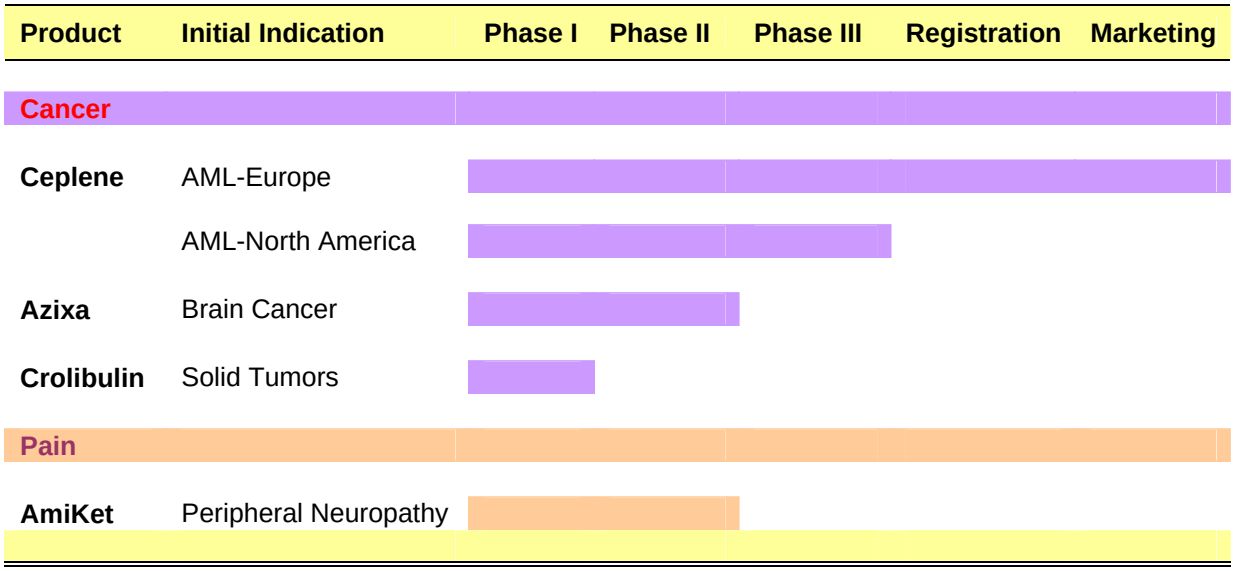
The Company's other oncology compounds include **crolibulin**, a novel small molecule vascular disruption agent (VDA), and apoptosis inducer for the treatment of patients with solid tumors and lymphomas. In December 2010, the NCI initiated a **Phase Ib/II** trial for crolibulin to assess safety and efficacy 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, **AmiKet** (formerly 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 AmiKet for post-herpetic neuralgia (PHN), diabetic peripheral neuropathy (DPN) and chemotherapy induced peripheral neuropathy (CIPN), respectively. All Phase II studies support the advancement of AmiKet into a registration-sized trial. EpiCept intends to partner AmiKet 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

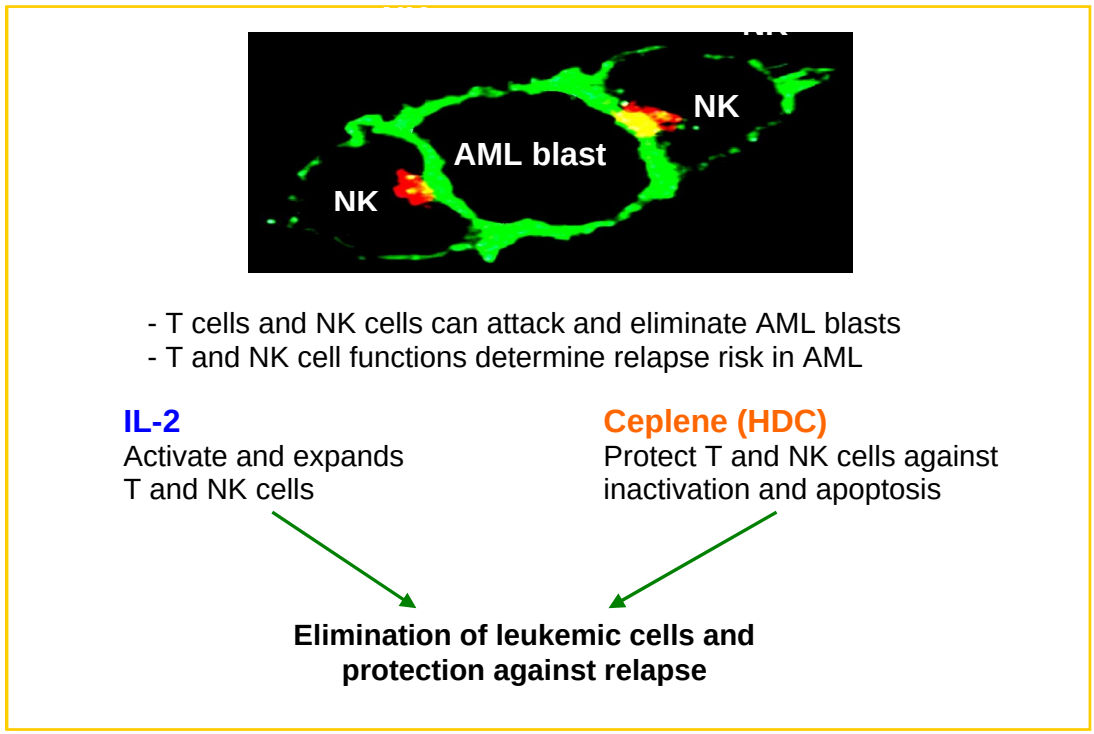
INVESTMENT THESES

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.

AmiKet: Targets Large Peripheral Neuropathy Market

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

AmiKet is ready for a pivotal Phase III trial

AmiKet 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). AmiKet 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. AmiKet 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 AmiKet 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 Amiket 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 Amiket 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 Amiket vs. placebo. Furthermore, the safety profile of Amiket was comparable to placebo.

In January 2009, the Company reported positive results from a **Phase IIb** clinical trial of AmiKet 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 Amiket achieved statistically significant superior efficacy compared with placebo ($p=0.026$). An additional primary endpoint, to demonstrate that Amiket 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 AmiKet 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 AmiKet achieved a superior safety profile when compared with gabapentin, especially with regard to dizziness and somnolence. In January 2010, AmiKet received orphan drug protection for the treatment of PHN.

In February 2008, the Company reported encouraging results from a Phase II clinical study of AmiKet in patients suffering from **diabetic peripheral neuropathy** (DPN). The trial was a double blind, placebo-

controlled study of AmiKet in 215 DPN patients who completed the trial. The data demonstrated that the primary endpoint, the difference in changes in pain intensity between AmiKet 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 AmiKet 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 AmiKet 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 AmiKet 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 AmiKet to a pivotal, registration-sized trial. EpiCept's plan is to find an appropriate **partner** to advance AmiKet 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 soon.

Market opportunity for AmiKet 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 AmiKet is targeting: diabetic peripheral neuropathy (DPN), post-herpetic neuropathy (PHN) and chemotherapy-induced peripheral neuropathy (CIPN), the market is huge for AmiKet.

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 AmiKet 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.

AmiKet 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 AmiKet 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 AmiKet a strong competitor in the PN market if approved. Furthermore, AmiKet may be used in combination with other therapies. Therefore, AmiKet 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 AmiKet 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.

In September 2011 Myrexis suspended further development of Azixa in order to advance lead candidates from its earlier stage programs, and has announced its intentions to out-license the compound. EpiCept will protect its rights to Azixa and share in any licensing proceeds while Myrexis seeks a partner to continue development.

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 maintain our Outperform rating on EpiCept Corp (EPCT) and reiterate our 12 month price target of $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 AmiKet 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 AmiKet 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 $0.34 per share which values the Company at about $24 million based on 71 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 $180 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, Sweden, Spain and other European countries
- Additional Meda regulatory filings
- Pivotal US survival trial for Ceplene to be initiated in 1H2012
- Crolibulin Phase Ib NCI combination trial results
- Completion of AmiKet partnership

On the business development side, the Company has been exploring potential partnership opportunities for its AmiKet 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 still 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 September 30, 2011 EpiCept had $10.6 million in cash and cash equivalents. Current cash is only sufficient to fund operations into second quarter of 2012. As the Company plans to initiate the US Phase

III trial of Ceplene, R&D costs will soar. We believe the Company may need to tap the capital market again as early as at the end of 2011. We remind investors, equity financing will dilute existing shareholder base, and share price will suffer.

However, EpiCept has been actively seeking partnership for its AmiKet program. With positive results from the Phase II clinical trials, it should not be difficult for the Company to land a lucrative partnership during 2012. 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 AmiKet, 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	Q1A	Q2A	Q3A	Q4E	FYE	FYE	FYE	FYE	FYE
Product Revenue	$0.00	$0.05	$0.02	$0.10	$0.17	$0.05	$0.00	$0.03	$0.15	$0.60	$1.75	$3.50	$8.00	$18.50
R&D revenue	$0.17	$0.20	$0.24	$0.19	$0.80	$0.19	$0.22	$0.24	$0.15	$0.80	$0.50	$0.50	$0.50	$0.50
Total Revenues	**$0.17**	**$0.25**	**$0.26**	**$0.29**	**$0.97**	**$0.24**	**$0.22**	**$0.28**	**$0.30**	**$1.04**	**$2.25**	**$4.00**	**$8.50**	**$19.00**
YOY Growth	*45.2%*	*175.8%*	*121.6%*	*216.3%*	*133.3%*	*42.5%*	*-10.8%*	*7.0%*	*3.1%*	*7.3%*	*845.4%*	*1685.7%*	*2990.9%*	*6233.3%*
CoGS	0.00	0.06	0.33	0.57	0.97	0.09	0.27	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)**	**$0.15**	**($0.05)**	**$0.22**	**$0.25**	**$0.58**	**$1.75**	**$3.00**	**$6.50**	**$15.40**
Gross Margin	*100.0%*	*75.3%*	*-29.6%*	*-96.9%*	*-0.2%*	*62.2%*	*-20.5%*	*81.5%*	*83.3%*	*55.5%*	*77.8%*	*75.0%*	*76.5%*	*81.1%*
SG&A	$2.06	$1.72	$1.86	$1.61	$7.25	$1.39	$2.04	$1.98	$2.00	$7.41	$8.50	$9.50	$12.00	$15.00
% SG&A	-	-	-	-	-	-	-	-	-	-	-	-	-	-
R&D	$2.04	$2.55	$2.08	$1.46	$8.13	$1.68	$1.99	$2.62	$3.20	$9.49	$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)**	**($2.9)**	**($4.1)**	**($4.4)**	**($5.0)**	**($16.3)**	**($18.8)**	**($19.0)**	**($20.5)**	**($11.6)**
Operating Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Other Net	($0.6)	($0.8)	$0.84	$0.4	($0.2)	$0.5	($0.3)	($1.0)	($0.2)	($1.0)	($0.8)	($0.8)	($1.0)	($1.0)
Pre-Tax Income	**($4.5)**	**($4.9)**	**($3.2)**	**($3.0)**	**($15.5)**	**($2.5)**	**($4.3)**	**($5.4)**	**($5.2)**	**($17.4)**	**($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)**	**($2.5)**	**($4.3)**	**($5.4)**	**($5.2)**	**($17.4)**	**($19.6)**	**($19.8)**	**($21.5)**	**($12.6)**
YOY Growth	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Net Margin	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Shares Out	*44.2*	*44.3*	*50.4*	*52.5*	*47.8*	*60.1*	*71.0*	*71.0*	*72.0*	*68.5*	*75.0*	*80.0*	*85.0*	*90.0*
Reported EPS	**($0.10)**	**($0.11)**	**($0.06)**	**($0.06)**	**($0.32)**	**($0.04)**	**($0.06)**	**($0.08)**	**($0.07)**	**($0.25)**	**($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*	*$0.62*	*$0.00*	*$0.62*	*$0.00*	*$0.00*	*$0.00*	*$0.00*
Non GAAP Net Income	**($4.5)**	**($4.9)**	**($3.2)**	**($3.0)**	**($15.5)**	**($2.5)**	**($4.3)**	**($4.8)**	**($5.2)**	**($16.7)**	**($19.6)**	**($19.8)**	**($21.5)**	**($12.6)**
Non GAAP EPS	**($0.10)**	**($0.11)**	**($0.06)**	**($0.06)**	**($0.32)**	**($0.04)**	**($0.06)**	**($0.07)**	**($0.07)**	**($0.24)**	**($0.26)**	**($0.25)**	**($0.25)**	**($0.14)**

Source: Company filings and Zacks Investment Research estimates

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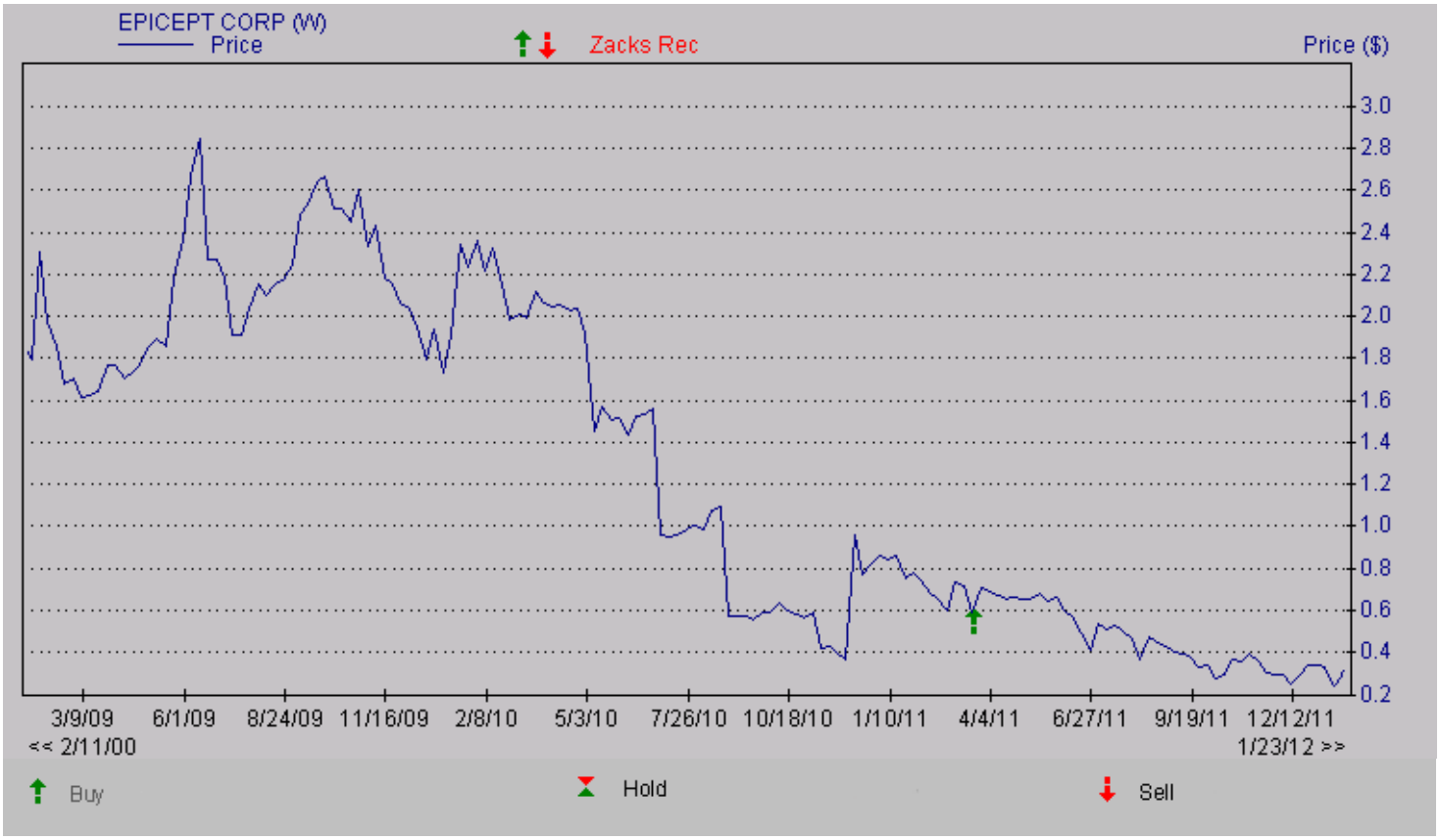
HISTORICAL ZACKS RECOMMENDATIONS



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