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# Ceplene in the Global Market

Ceplene, when used concomitantly with low-dose interleukin-2, is indicated for remission maintenance and prevention of relapse in the treatment of Acute Myeloid Leukemia (AML) in patients who are in their first remission. Ceplene has been approved in the European Union; the Company's marketing partner, Meda AB, will begin selling Ceplene in 2010. Marketing applications have been submitted in Canada and Israel. A US New Drug Application (NDA) is expected to be filed in 2010. Ceplene has received orphan drug designation in the European Union and the United States.

♠ Approved—European Union, Iceland, Norway, Liechtenstein
♠ Filed—Canada, Israel
♠ Filing in 2010—United States



EpiCept is focused on the development and commercialization of pharmaceutical products for the treatment of cancer and pain. In addition to Geplene, the Company has two encology drug candidates currently in clinical development that were discovered using in-house technology and have been shown to act as vascular disruption agents in a variety of solid tumors. The Company's pain portfolio includes EpiCept<sup>TM</sup> NP-1, a prescription topical analgesic cream in late-stage clinical development designed to provide effective long-term relief of pain associated with peripheral neuropathies. EpiCept is headquartered in Tarrytown, New York, and has a satellite office in Munich, Germany. EpiCept is listed on the Nasdaq Capital Market and on the Nasdaq OMX Stockholm Exchange under the symbol "EPCT".





Robert G. Savage, Chairman of the Board & Jack V. Talley, President & Chief Executive Officer

# The last twelve months have been a time of great progress and excitement for EpiCept.

EpiCept continues to make progress and deliver major achievements for our shareholders. When we first went public in January 2006 we laid out a clear and bold vision to gain approval for Ceplene® (histamine dihydrochloride) in the European Union. Once that was achieved, we laid out the vision of securing a credible, dynamic marketing partner. Meda AB is that partner. We now approach the seminal events of North American regulatory filing and approval for Ceplene in remission maintenance of acute myeloid leukemia (AML). These are indeed exciting times for all of us.

The promise that was inherent in our approval in Europe for Ceplene came closer to reality this past January with

the finalization of a successful and valuable commercialization agreement for this new therapeutic breakthrough. As a result, Ceplene is being commercially launched and made readily available to AML patients in their first remission in the United Kingdom, Germany and several other European countries and will be systematically rolled out throughout Europe. To underscore the therapeutic significance of Ceplene, we noted with a sense of accomplishment that the EMEA, in the summary of its Annual Report for 2008 stated, "Of the 66 medicines to receive a positive opinion from the CHMP in 2008, those that are of particular note include: the first medicine for use as a maintenance

treatment in adults with acute myeloid leukemia..."

With an experienced marketing partner now in place to handle the commercial activities of Ceplene in Europe, for the balance of 2010 we will focus on expanding the benefits of Ceplene to new geographic markets as well as into new indications. We believe execution of the strategies we have in place to achieve these goals will serve as a vital gateway in our continued ascent to a self-funding, profitable, hematology-focused enterprise in North America.

We are diligently preparing for key regulatory milestones expected to take place in 2010 for Ceplene in North America. A New Drug Submission

# **EpiCept Corporation**





(NDS) for Ceplene is currently under active review by officials from Health Canada, with a decision expected late in the third quarter of this year. In addition, we are nearing completion of the New Drug Application (NDA) for the therapy in the United States, which we anticipate filing this quarter.

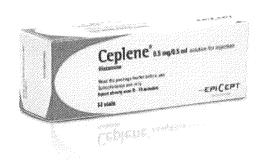
We continue to be very optimistic at the commercial prospects for Ceplene in North America. In the U.S. alone, there are an estimated 7,000 new AML patients annually that would be potential candidates for the Ceplene/IL-2 treatment regimen, equaling a commercial market

by exploring the benefit of its use in combination with currently marketed drugs. Two new studies for Ceplene are expected to take place this year that will aid us in achieving this goal. The first will examine the effects of Ceplene and low-dose IL-2 in combination with Vidaza® (azacitidine) in the treatment of patients with higherrisk myelodysplastic syndrome, a bone marrow disease that can progress to AML. The study will be led by the Groupe Francophone des Myelodysplasies, with enrollment expected to commence later this year. This study would likely be followed by

of minimal residual disease (MRD) in patients with chronic myeloid leukemia. This study is being developed by the Nordic Chronic Myeloid Leukemia Study Group, which is comprised of physicians and researchers in Sweden, Denmark, Norway and Finland. We expect this trial to commence enrollment later this year as well.

We are also moving forward with the post-approval clinical study of Ceplene initiated in July 2009 that is studying the effects of remission maintenance therapy with Ceplene/ IL-2 on immune activation and MRD emergence in adult patients with AML

Ceplene received approval in the European Union and will be launched commercially beginning in April 2010. Ceplene is currently under review in Canada and Israel and will be filed in the U.S. in 2010, with approval possible in 2011.



potential of more than \$200 million. Furthermore, there continues to be no competing products in late-stage development. Our competitive position is further bolstered by the orphan drug protection granted to Ceplene in the U.S. as well as in Europe.

In 2010, we also intend to execute on our strategy to expand Ceplene's label a randomized Phase II study comparing the efficacy, safety and tolerability of the addition of Ceplene/IL-2 to Vidaza compared to Vidaza alone.

The second study will be a Phase I/II study that will research the effects of a regimen of Ceplene and low-dose IL-2 in combination with Gleevec® (imatinib mesylate) on the eradication

in first complete remission. This openlabel, multicenter study will also assess the quantitative and qualitative pharmacodynamic effects of Ceplene/ IL-2 on these patients by monitoring T and natural killer cell phenotypes and their functionality after the first and third treatment cycles. This ongoing study will enroll up to 150 patients at approximately 30 centers across



Europe, with sites in Sweden, Belgium, France, the U.K., Spain and Italy.

## A Valuable Pain Candidate

We believe 2010 will also mark a watershed in the advancement of EpiCept™ NP-1, a Phase III-ready topical prescription analgesic cream designed to provide long-term relief from the pain of peripheral neuropathies, which affects more than 15 million people in the U.S. alone.

EpiCept NP-1 is a highly researched treatment candidate, having been studied in over 1,300 patients in seven clinical trials to date. In its most recently completed trial, a 360-patient Phase IIb active comparator clinical trial in patients with post-herpetic neuralgia (PHN), NP-1 achieved statistically significant pain relief as compared to placebo and was statistically similar in pain relief to the market leader, gabapentin, and with fewer side effects.

Earlier this year, we announced that NP-1 had received an orphan drug designation in the U.S. for the treatment of PHN, providing us with marketing exclusivity for seven years. Orphan drug designation may also have value in the NDA filing and review process.

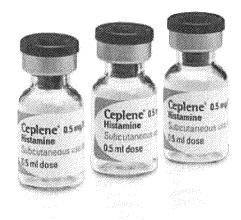
We are currently in the process of securing a partner for NP-1 to share in the development costs and ultimately market the product globally. We believe NP-1 represents an exciting opportunity. It is estimated that the market size for treatments for peripheral neuropathies in the U.S. alone

will be \$5 billion by 2018, buoyed by positive demographics and the limitations of current therapies. We have been pleased with the interest shown by potential partners to date and look forward to updating you on this selection process as the year progresses.

## A Promising Cancer Pipeline

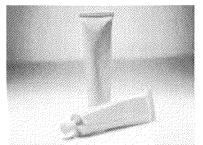
In 2010, we also intend to continue the progress made with crolibulin™ (EPC2407), our vascular disruption agent (VDA) that has demonstrated superior anti-tumor activity compared to other VDAs in both preclinical and early clinical studies. Last year, we successfully completed a Phase la study for the compound that determined its maximum tolerated dose and provided evidence of clinical symptomatic activity and radiographic evidence of efficacy in end-stage cancer patients. In 2010, we intend to initiate a Phase Ib trial for the compound in combination with the standard dose of appropriate chemotherapy in several solid tumor types.

We also anticipate that additional clinical progress will be shared in 2010 on Azixa<sup>™</sup>— a compound discovered by EpiCept and licensed to Myriad Genetics Inc. as part of an exclusive, worldwide development and commercialization agreement. In November 2009, Myriad Pharmaceuticals announced interim results of one of its Phase II trials of Azixa in melanoma metastases in which 10 of the 22 patients treated achieved stable disease and two patients achieved confirmed partial responses. These



40%

40% of Ceplene-treated patients in first remission were leukemia free at 3 years vs. 26% of control patients, a statistically significant result. A median improvement of 64 weeks was seen in overall survival.





EpiCept™ NP-1 Phase II development has demonstrated proven analysesic activity and the product is ready for global partnering. U.S. orphan drug protection in post-herpetic neuralgia was obtained in early 2010.

impressive results in our view alone merit advance to Phase III trials. The continued advancement of Axiza represents a valuable revenue-generating opportunity for us, with the dosing of the first patient in a Phase III trial for Azixa triggering the next milestone payment, which we anticipate will occur in 2010.

# Confidence in the Future

2009 was a year in which we made substantial progress towards our goal of transforming EpiCept into a profitable, oncology-focused, specialty pharmaceutical company. Our confidence and excitement grow with each step as we approach that goal's realization. We have sought to infuse our confidence and enthusiasm with our quarterly conference calls and the many investor presentations we made throughout the year. While we are pleased with the Company's progress to date, we recognize the many challenges that lay ahead, and we welcome your support in 2010 and beyond.

# Looking Forward

We are keenly aware of the need to continue to be highly efficient with our resources and to preserve our capital. In 2010, we will continue to focus on the advancement of our most promising candidates in our pipeline and on regulatory pursuits that provide the highest near-term growth potential for our Company.

We have a clear path forward to build value for our shareholders in the coming year. This path forward is focused on the following objectives:

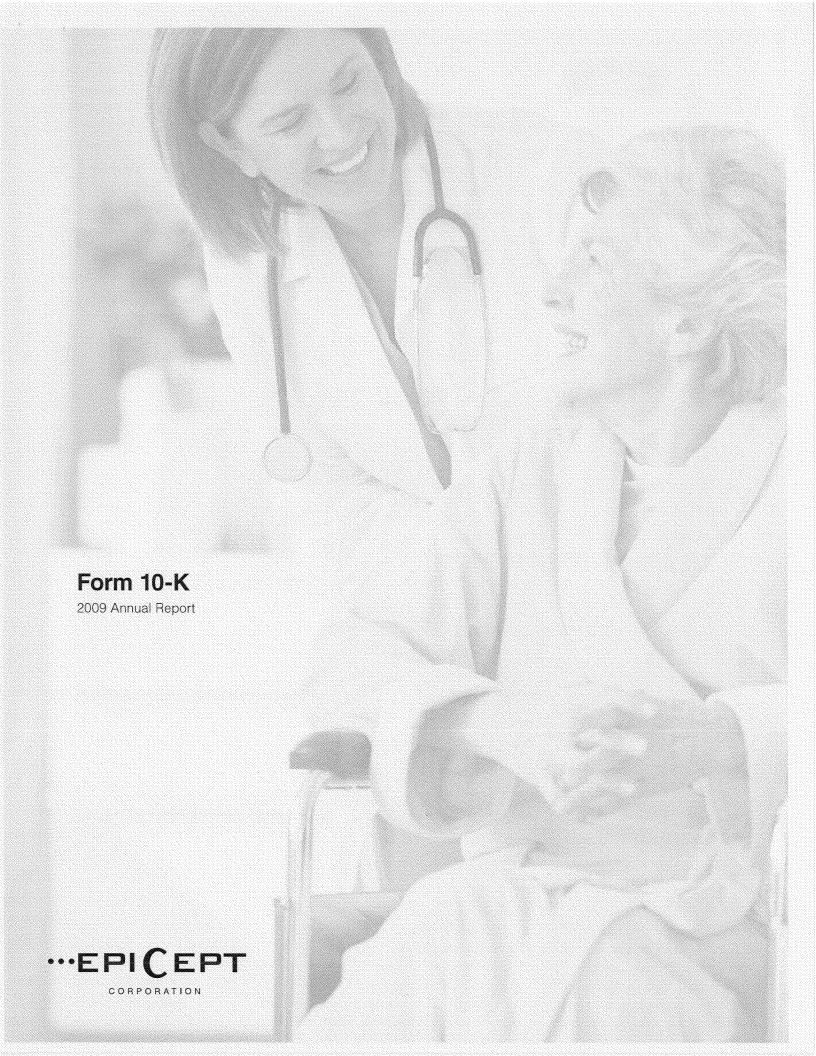
- Successfully launch Ceplene in Europe
- File an NDA for Ceplene in the U.S.
- Receive a decision on the NDS filing for Ceplene in Canada
- Secure a partner for EpiCept NP-1
- Share progress from our partner Myriad's Phase II brain cancer trial for Azixa, and
- Initiate the Phase Ib combination trial for crolibulin.

2010 is poised to be a pivotal year in our evolution towards becoming a growing and profitable commercial enterprise. We believe we have the talents, assets and strategy needed to capitalize on all of the opportunities before us. In conclusion, we would like to thank our employees for their continued dedication and contributions to EpiCept, without which our continued success would not be possible.

Robert G. Savage Chairman of the Board

Jack V. Talley
President and Chief Executive Officer

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# **Corporate Information**

Executive Officers

Jack V. Talley President and Chief Executive Officer

Robert W. Cook Chief Financial Officer and

Dileep Bhagwat, Ph.D. Senior Vice President. Pharmaceutical Development

Stephane Allard, M.D. **Chief Medical Officer** 

Bernard R. Tyrell Senior Vice Presiden Sales and Marketing

Oliver Wiedemann, M.D. Managing Director, Medical Affairs Board of Directors

Robert G. Savage

Jack V. Tailey Guy C. Jackson

Gerhard Waldheim

Wayne P. Yetter

A. Collier Smyth, M.D.

Transfer Agent American Stock Transfer & Trust Company 59 Maiden Lane

Shares Listed

Independent Registered Public Accountants Deloitte & Touche LLP Two Hilton Court Parsippany, NJ 07054

Corporate Counsel Ellenberg and Krause LLP 11 E. 44th Street

Investor Relations

Media and Public Relations Feinstein Kean Healthcare 245 First Street Cambridge, MA 02142

Sveavägen 20

Investor Relations

Additional copies of this Annual Report and of the Company's Report on Form 10-K, excluding exhibits, are available without charge, along with ancillary company materials for invest-

**EpiCept Corporation** 

EpiCept Annual Report—Safe Harbor Language

This annual report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements which express plans, articipation, intent, contingency, goals, targets, or future development and are otherwise not statements of historical fact. These statements are based on our current expectations and are subject to risks and uncertaintiles that could cause actual results or developments to be materially different from historical results or formany future results expressed or implied by such forward-looking statements. Factors that may cause actual results or developments to differ materially include the risk that Ceplene\* will not receive regulatory approval or marketing sulthorization in the United States or Canada, the risk that Ceplene\* will not achieve significant commercial success the risk that any required post-approval clinical study for Ceplene\* will not he successful. The risk that we will not be able to maintain our final regulatory approval or marketing authorization for Ceplene\*, the risks associated with fire adequacy of our existing death resolutes and our ability to continue as a going concern, the risks associated with fire adequacy of our existing death resolutes and our ability to continue as a going concern, the risks associated with our adequacy of our existing death appeared to the risk that Actual and provide an approval or achieve significant payments under our agreements, the risk that Actual and provide receive any significant payments under our agreements, the risk that Actual and provide receive any significant payments under our agreement with Mixida, the risk that be evelopment of our other arroptacle candidates will not be successful, the risk that commercial success, the risk that we will not receive regulatory approval to not demonstrate safety and/for-afficacy in large-scale or later stage chiral commercial success, the risk that our other product ca

# ...EPI CEPT

CORPORATION

Corporate Headquarters 777 Old Saw Mill River Rd. Tarrytown, NY 10591 Phone: 914-606-3500

# Germany

Goethestraße 4 D-80336 Munich, Germany Phone: 011-49-89-680872-0

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