



## CONTACTS

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## **EPICEPT REPORTS SECOND QUARTER 2012 OPERATING AND FINANCIAL RESULTS**

*CONFERENCE CALL BEGINS AT 9:00 A.M. EASTERN TIME TODAY*

**TARRYTOWN, N.Y. (August 8, 2012)** – EpiCept Corporation (Nasdaq OMX Stockholm Exchange and OTCQX: EPCT) today reported net income of \$3.0 million for the three months ended June 30, 2012 and a reduced net loss for the six months ended June 30, 2012 to \$0.6 million, primarily as a result of the Company's sale of its Ceplene<sup>®</sup>-related assets and contract rights to Meda AB. The net loss for the three and six month periods ended June 30, 2011 was \$4.3 million and \$6.8 million, respectively. The Company also provided an update on the Company's key business initiatives.

"EpiCept achieved an important strategic goal during the second quarter of 2012 by completing the sale of our rights to Ceplene<sup>®</sup> for Europe and several Asia Pacific countries to Meda," remarked Jack Talley, President and Chief Executive Officer. "We pursued this course of action after concluding that for at least the next several years Ceplene<sup>®</sup> is unlikely to generate sufficient revenue for us to fund the ongoing post-approval trial and the requirements for product manufacturing. By completing the transaction with Meda we not only received cash to help fund our ongoing operations, but we also freed ourselves of millions of dollars of future Ceplene obligations that we would have had to fund via additional debt or equity financing. Additionally we have implemented several initiatives in terms of reduced head count and other operating activities to reduce our cash burn as evidenced in the year to year comparisons."

### **Business Highlights**

- Sold all rights to Ceplene<sup>®</sup> in the territories previously licensed to Meda AB, and a portion of its remaining Ceplene<sup>®</sup> inventory, to Meda for approximately \$2.6 million in net cash and the assumption of EpiCept's ongoing responsibilities related to the manufacture of and maintenance of the marketing authorization for Ceplene<sup>®</sup> in the European Union.

- Received written advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in June concerning the clinical and nonclinical development and subsequent Marketing Authorization Approval (MAA) filing of AmiKet™ for the treatment of chemotherapy-induced peripheral neuropathy (CIPN) that was broadly consistent with guidance received from the FDA earlier this year.
- Granted Fast Track Status by the U.S. Food and Drug Administration (FDA) for AmiKet™ for the treatment of CIPN. The FDA's Fast Track program is designed to facilitate the development and expedite the review of drugs intended to treat serious or life-threatening conditions and address unmet medical needs. Fast Track may reduce the standard review time of a New Drug Application by half.
- New preclinical research for the licensed apoptosis inhibitor drug candidate F573 (previously named EP1013) concluded that F573 is a new therapeutic drug candidate for the treatment of late-stage viral infection-induced hepatitis. The data were published in the Chinese Pharmacological Bulletin (2102 Volume 28 (1):136-139). F573 was discovered by EpiCept and licensed to GNI Group Ltd. in 2008 for clinical development in Asia, Australia and New Zealand.

### **Product Portfolio Update**

- Ceplene® - approved in the EU and Israel for administration with low-dose interleukin-2 (IL-2) for the remission maintenance and prevention of relapse of patients with Acute Myeloid Leukemia (AML) in first remission; AML is the deadliest form of leukemia in adults. In June 2012, the Company sold all of its rights to Ceplene® in the territories previously licensed to Meda AB, and a portion of its remaining Ceplene® inventory, to Meda for approximately \$2.6 million in cash and the assumption of EpiCept's ongoing responsibilities related to the manufacture of, and maintenance of the marketing authorization for, Ceplene® in the European Union. EpiCept also agreed to relinquish all future milestone payments and royalties on future sales of Ceplene® by Meda. In conjunction with the closing of this transaction EpiCept will close its EpiCept GmbH facility in Munich, Germany over the next several months. Ceplene® is licensed to Megapharm Ltd. to market and sell in Israel. Following Ministry of Health approval of labeling and other reimbursement matters expected this year, Megapharm Ltd. is expected to commence the commercial launch of Ceplene® in Israel, until which time it is available there on a named-patient basis. EpiCept retains rights to Ceplene® in all other countries, including countries in North and South America.
- AmiKet™ - a prescription topical analgesic cream designed to provide long-term relief from the pain of peripheral neuropathies, which affect more than 15 million people in the U.S. alone. During the second quarter of 2012, EpiCept received written advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) concerning the clinical and nonclinical development and subsequent Marketing Authorization Approval (MAA) filing of AmiKet™. In its written advice the CHMP recommended that the proposed clinical program consist of a single 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. An additional two-arm efficacy study in CIPN or another neuropathy is required to complete the clinical requirements of the application. The advice provided a summary of the additional nonclinical program requirements to file an

MAA, which included a 90-day dermal toxicity study in a non-rodent species, a dermal phototoxicity study in a rodent and an ocular toxicity study. The advice received from the CHMP is consistent with the guidance given to the Company by the FDA in January 2012, in which 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 FDA granted Fast Track Status to AmiKet™ in April 2012 and has agreed that a Special Protocol Assessment (SPA) would be available upon formal submission and agreement on the Phase III trial protocol.

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.

- F573 (previously known as EP1013) - a di-peptide small-molecule compound licensed by EpiCept to GNI Group Ltd. in China, Japan and other key Asian territories that has demonstrated a potent inhibitory effect on caspases, a class of enzymes involved in cell death and inflammation. Drug efficacy has been shown in animal models relating to liver failure, brain ischemia and myocardial infarction. Data published in the Chinese Pharmacological Bulletin (2102 Volume 28 (1):136-139) during the first quarter of 2012 concluded that F573 is a new therapeutic drug candidate for the treatment of late-stage viral infection-induced hepatitis. F573 delivered intravenously demonstrated a therapeutic effect in a study involving 60 mice with acute liver injury, including a reduction in TNF- $\alpha$  and cell apoptosis. As part of its license agreement with GNI Group Ltd., EpiCept received a small upfront fee upon signing the agreement and is eligible to receive milestone payments of more than \$12 million based on the clinical advancement of F573 in the licensed territories, as well as royalties on commercial sales. EpiCept retains the commercial rights to F573/EP1013 in all other markets. The next potential milestone payment will be in conjunction with initiation of a Phase I trial in any of the territories outlined in the agreement. In July 2011 Shanghai Genomics, a wholly owned subsidiary of GNI Group Ltd., filed an Investigational New Drug (IND) application for F573 in China.
- Crolibulin™ - a vascular disruption agent that has demonstrated potent anti-tumor activity in both preclinical and early clinical studies. In December 2010 the NCI initiated a Phase Ib/II trial with crolibulin™ to assess safety and efficacy in combination with cisplatin in patients with anaplastic thyroid cancer. Trial enrollment has progressed to the third and final dosing cohort for the Phase Ib portion of this trial. The Phase II randomized proof-of-concept efficacy portion of the trial is anticipated to begin later in 2012.
- Azixa™\* - a vascular disruption agent 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. In February 2012 Myrexis suspended development activities of all its preclinical and clinical programs in oncology and autoimmune diseases, and in May 2012 the company stated that it is focused on the identification, evaluation and acquisition of appropriate commercial-stage assets. EpiCept believes that in light of its new strategic

direction, Myrexix does not intend to comply with its development obligations; therefore, the Company intends to enforce its rights under the license agreement with Myrexix.

### **Financial and Operating Highlights**

EpiCept's net income attributable to common stockholders for the second quarter of 2012 was \$2.2 million, or \$0.03 per diluted share, compared with a net loss attributable to common stockholders of \$4.3 million, or \$0.06 per share, for the second quarter of 2011. Net income attributable to common stockholders for the second quarter of 2012 includes \$0.8 million of deemed dividends on convertible preferred stock. EpiCept's net loss attributable to common stockholders for the six months ended June 30, 2012 was \$2.5 million, or \$0.03 per share, compared with a net loss of \$6.8 million, or \$0.10 per share, for the six months ended June 30, 2011. The net loss attributable to common stockholders for the six months ended June 30, 2012 includes \$1.9 million of deemed dividends on convertible preferred stock.

### **Second Quarter and Six Months 2012 vs. Second Quarter and Six Months 2011**

#### ***Revenue***

The Company recognized revenue of \$6.6 million during the second quarter of 2012, compared with \$0.2 million during the second quarter of 2011. The Company recognized revenue of \$6.8 million during the six months ended June 30, 2012, compared with \$0.5 million during the six months ended June 30, 2011. For the second quarter of 2012, revenue consisted primarily of license fee payments and product revenue from the sale of the Company's rights to Ceplene<sup>®</sup> to Meda AB. For the second quarter of 2011, revenue consisted primarily of the recognition of license fee payments previously received from strategic alliances.

#### ***Cost of Goods Sold***

Cost of goods sold in the second quarter of 2012 consisted solely of the costs from the sale of Ceplene<sup>®</sup> to Meda AB. Cost of goods sold in the second quarter of 2011 consisted primarily of a \$0.3 million expense for Ceplene<sup>®</sup> inventory the Company believed would not be sold prior to reaching its product expiration date. Cost of goods sold was \$0.4 million for each of the six months ended June 30, 2012 and 2011.

#### ***Selling, General and Administrative (SG&A) Expense***

SG&A expense in the second quarter of 2012 decreased by approximately 30%, or \$0.6 million, to \$1.4 million, compared with \$2.0 million in the second quarter of 2011. The decrease was primarily attributable to lower legal expenses, lower salary and salary related expenses as the result of a reduction in projected bonus payments for 2012 and lower investor relations expenses. SG&A expense for the six months ended June 30, 2012 decreased by approximately 18%, or \$0.6 million, to \$2.8 million, compared with \$3.4 million for the six months ended June 30, 2011. 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.

#### ***Research and Development (R&D) Expense***

R&D expense in the second quarter of 2012 decreased by 50%, or \$1.0 million, to \$1.0 million from \$2.0 million in the second quarter of 2011. R&D expense for the six months ended June 30, 2012 decreased by approximately 38%, or \$1.4 million, to \$2.3 million, compared with \$3.7 million for the six months ended June 30, 2011. The decrease was primarily attributable to lower clinical trial costs for Ceplene<sup>®</sup>, lower salary and salary related expenses and lower patent expenses. Our clinical efforts during the second quarters of 2012 and 2011 were focused on our

open label trial of Ceplene<sup>®</sup> that is intended to meet our post-approval requirements with the EMA. . We expect research and development expenses to remain at approximately current levels over the next few quarters.

### ***Other Income (Expense)***

Other income (expense) during the second quarter of 2012 was net expense of \$0.9 million, compared with net expense of \$0.3 million in the second quarter of 2011. Other expense for the six months ended June 30, 2012 was \$1.9 million, compared with other income of \$0.2 million for the six months ended June 30, 2011. The primary components of other expense in 2012 were warrant amendment expense of \$0.9 million, interest expense of \$0.7 million related primarily to the Company's senior secured term loan and a foreign exchange loss. Other income, net for the six months ended June 30, 2011 was impacted by a \$0.7 million foreign exchange gain incurred as a result of the decreased value of the U.S. dollar compared with the euro, which was partially offset by interest expense of \$0.5 million.

### **Liquidity**

EpiCept had \$4.8 million in cash and cash equivalents as of June 30, 2012. The Company engaged SunTrust Robinson Humphrey in January 2012 to assist in exploring strategic alternatives to maximize the commercial opportunity of AmiKet<sup>™</sup> for the treatment of CIPN following taxane-based therapy. The engagement is focused on the identification and implementation of a strategy designed to optimize AmiKet<sup>™</sup>'s value for the Company's stockholders, which includes the evaluation of potential transactions involving the sale of the Company. EpiCept is considering various transactions to obtain additional cash resources to fund operations and clinical trials, including the sale or licensing of assets and the sale of equity securities. Current cash is anticipated to be sufficient to run operations into the fourth quarter of 2012. If EpiCept is unable to complete a transaction or otherwise obtain funding on a timely basis, the Company may be forced to further reduce expenses or curtail operations. See our Quarterly Report on Form 10-Q for the period ended June 30, 2012 for a further discussion of the Company's liquidity and cash position.

### **Conference Call**

EpiCept will host a conference call to discuss these results and answer questions on August 8, 2012 beginning at 9:00 a.m. Eastern time.

To participate in the live call, please dial from the United States or Canada (877) 809-8594 or from international locations (706) 758-9407 (please reference access code 17527052). The conference call will also be broadcast live in listen-only mode on the Internet and may be accessed at [www.epicept.com](http://www.epicept.com). The webcast will be archived for 90 days.

A telephone replay of the call will be available for seven days by dialing from the United States or Canada (855) 859-2056 or from international locations (404) 537-3406 (please reference reservation number 17527052).

### **About EpiCept Corporation**

EpiCept is focused on the development and commercialization of pharmaceutical products for the treatment of pain and cancer. The Company's pain portfolio includes AmiKet<sup>™</sup>, a prescription topical analgesic cream in late-stage clinical development designed to provide effective long-term relief of pain associated with peripheral neuropathies. The Company's product Ceplene<sup>®</sup>, when

used concomitantly with low-dose IL-2 is intended as remission maintenance therapy in the treatment of AML for adult patients who are in their first complete remission. The Company sold all of its rights to Ceplene<sup>®</sup> in Europe and certain Pacific Rim countries and a portion of its remaining Ceplene<sup>®</sup> inventory to Meda AB in June 2012. Ceplene<sup>®</sup> is licensed to MegaPharm Ltd. to market and sell in Israel and EpiCept has retained its rights to Ceplene<sup>®</sup> in all other countries, including countries in North and South America. The Company has other oncology drug candidates 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.

### **Forward-Looking Statements**

This news release and any oral statements made with respect to the information contained in this news release contain forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements which express plans, anticipation, intent, contingency, goals, targets, future development and are otherwise not statements of historical fact. These statements are based on our current expectations and are subject to risks and uncertainties that could cause actual results or developments to be materially different from historical results or from any future results expressed or implied by such forward-looking statements. Factors that may cause actual results or developments to differ materially include: the risks associated with the adequacy of our existing cash resources and our ability to continue as a going concern, the risks associated with our ability to continue to meet our obligations under our existing debt agreements, the risk that Azixa<sup>™</sup> will not receive regulatory approval or achieve significant commercial success, the risk that we will not receive any significant payments under our agreement with Myrexix, the risk that clinical trials for AmiKet<sup>™</sup> or crolibulin<sup>™</sup> will not be successful, the risk that AmiKet<sup>™</sup> or crolibulin<sup>™</sup> will not receive regulatory approval or achieve significant commercial success, the risk that we will not be able to find a partner to help conduct the Phase III trials for AmiKet<sup>™</sup> on attractive terms, a timely basis or at all, the risk that Ceplene<sup>®</sup> will not receive regulatory approval or marketing authorization in the United States or Canada, the risk that Ceplene<sup>®</sup> will not achieve significant commercial success, the risk that our other product candidates that appeared promising in early research and clinical trials do not demonstrate safety and/or efficacy in larger-scale or later-stage clinical trials, the risk that we will not obtain approval to market any of our product candidates, the risks associated with dependence upon key personnel, the risks associated with reliance on collaborative partners and others for further clinical trials, development, manufacturing and commercialization of our product candidates; the cost, delays and uncertainties associated with our scientific research, product development, clinical trials and regulatory approval process; our history of operating losses since our inception; the highly competitive nature of our business; risks associated with litigation; and risks associated with our ability to protect our intellectual property. These factors and other material risks are more fully discussed in our periodic reports, including our reports on Forms 8-K, 10-Q and 10-K and other filings with the U.S. Securities and Exchange Commission. You are urged to carefully review and consider the disclosures found in our filings which are available at [www.sec.gov](http://www.sec.gov) or at [www.epicept.com](http://www.epicept.com). You are cautioned not to place undue reliance on any forward-looking statements, any of which could turn out to be wrong due to inaccurate assumptions, unknown risks or uncertainties or other risk factors.

**Selected financial information follows:**

**EpiCept Corporation and Subsidiaries  
(Unaudited)  
Selected Consolidated Balance Sheet Data  
(in \$000s)**

	<u>June 30,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
Cash and cash equivalents	\$ 4,773	\$ 6,378
Inventory	6	360
Property and equipment, net	84	120
Total assets	\$ 5,302	\$ 7,521
Accounts payable and other accrued liabilities	\$ 3,276	\$ 3,333
Deferred revenue	8,700	12,947
Notes and loans payable	5,630	8,022
Total stockholders' deficit	(12,557)	(17,146)
Total liabilities and stockholders' deficit	\$ 5,302	\$ 7,521

**EpiCept Corporation and Subsidiaries  
(Unaudited)  
Selected Consolidated Statement of Operations Data  
(in \$000s except share and per share data)**

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>
Product net revenues	\$ 577	\$ 1	\$ 583	\$ 1
Licensing and other revenues	6,025	223	6,260	461
<b>Total net revenues</b>	<u>6,602</u>	<u>224</u>	<u>6,843</u>	<u>462</u>
<b>Operating expenses:</b>				
Cost of product net revenues	396	270	396	360
Selling, general and administrative	1,384	2,042	2,815	3,436
Research and development	963	1,991	2,259	3,675
Total operating expenses	<u>2,743</u>	<u>4,303</u>	<u>5,470</u>	<u>7,471</u>
Income (loss) from operations	<u>3,859</u>	<u>(4,079)</u>	<u>1,373</u>	<u>(7,009)</u>
<b>Other income (expense):</b>				
Interest income	1	4	3	6
Foreign exchange (loss) gain	(521)	155	(264)	659
Warrant amendment expense	—	—	(936)	—
Interest expense	(380)	(422)	(743)	(461)
Other income (expense), net	(900)	(263)	(1,940)	204
<b>Net income (loss) before income taxes</b>	<u>2,959</u>	<u>(4,342)</u>	<u>(567)</u>	<u>(6,805)</u>
Income taxes	—	—	(2)	(3)
<b>Net income (loss)</b>	<u>\$ 2,959</u>	<u>\$ (4,342)</u>	<u>\$ (569)</u>	<u>\$ (6,808)</u>
Deemed dividends on convertible preferred stock	(750)	—	(1,926)	—
<b>Income (loss) attributable to common stockholders</b>	<u>\$ 2,209</u>	<u>\$ (4,342)</u>	<u>\$ (2,495)</u>	<u>\$ (6,808)</u>
Basic and diluted income (loss) per common share	<u>\$ 0.03</u>	<u>\$ (0.06)</u>	<u>\$ (0.03)</u>	<u>\$ (0.10)</u>
Weighted average shares - Basic	83,772,960	70,993,924	80,414,692	65,578,505
Weighted average shares - Diluted	91,591,893	70,993,924	80,414,692	65,578,505

**EpiCept Corporation and Subsidiaries**  
**(Unaudited)**  
**Selected Consolidated Statement of Cash Flows Data**  
**(in \$000s)**

	<b><u>Six Months Ended June 30,</u></b>	
	<b><u>2012</u></b>	<b><u>2011</u></b>
Net cash used in operating activities	\$ (2,599)	\$ (6,344)
Net cash provided by investing activities	—	116
Net cash provided by financing activities	1,003	18,362
Effect of exchange rate changes on cash	(9)	9
Net (decrease) increase in cash and cash equivalents	(1,605)	12,143
Cash and cash equivalents at beginning of year	6,378	2,435
Cash and cash equivalents at end of year	<u>\$ 4,773</u>	<u>\$ 14,578</u>

**EpiCept Corporation and Subsidiaries**  
**(Unaudited)**  
**Selected Consolidated Statement of Stockholders' Deficit Data**  
**(in \$000s)**

	<b><u>Six Months Ended June 30,</u></b>	
	<b><u>2012</u></b>	<b><u>2011</u></b>
Stockholders' deficit at beginning of year	\$ (17,146)	\$ (14,135)
Net loss for the period	(569)	(6,808)
Stock-based compensation expense	404	500
Foreign currency translation adjustment	257	(698)
Share and warrant issuance	2,833	11,416
Warrant amendment expense	936	—
Exercise of warrants	728	—
Stockholders' deficit at end of year	<u>\$ (12,557)</u>	<u>\$ (9,725)</u>

EpiCept had 84,088,023 shares outstanding as of July 31, 2012. EpiCept expects to release its interim results for the period ending September 30, 2012 on or about November 10, 2012.

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*\*Azixa is a registered trademark of Myrexix, Inc.*

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