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# EpiCept Reports Fourth Quarter and Full Year 2012 Operating and Financial Results

TARRYTOWN, N.Y.--(BUSINESS WIRE)-- Regulatory News:

EpiCept Corporation (Nasdaq OMX Stockholm Exchange and OTCQX: EPCT) today announced operating and financial results for the fourth quarter and full year ended December 31, 2012, and provided an update on the Company's merger with Immune Pharmaceuticals, Ltd. (Immune).

Robert Cook, Interim President and CEO of EpiCept, commented, "While we are focused on completing the merger with Immune that we announced in November 2012, we also remain committed to advancing our clinical programs to the greatest extent possible. We are working with the National Cancer Institute to initiate the second phase (the Phase II portion) of its study of crolibulin™ in the treatment of anaplastic thyroid cancer. Also, in conjunction with Immune we have renewed talks with several prospective partners concerning the potential out-licensing of AmiKet™. We remain very enthusiastic about the proposed merger with Immune Pharmaceuticals as we believe this transaction will provide EpiCept shareholders the opportunity both to benefit from the further development of EpiCept's pipeline and to share in the enormous potential that exists in Immune's pipeline with bertilimumab and the NanomAb® technology. We expect to close the transaction in the second quarter of 2013."

## **Business Highlights**

• Immune Pharmaceuticals Ltd., a privately held Israeli company, and EpiCept entered into a definitive merger agreement on November 7, 2012. The transaction, as amended, is anticipated to close during the second quarter of 2013 and is subject to satisfaction of certain customary closing conditions, including approval by a majority of EpiCept shareholders. The combined company will be focused on developing antibody therapeutics and other targeted drugs for the treatment of inflammatory diseases and cancer. Immune's lead product candidate, bertilimumab, is a fully human monoclonal antibody that targets eotaxin-1, a chemokine involved in eosinophilic inflammation, angiogenesis and neurogenesis. Immune is currently initiating, following authorization from Israeli health authorities, a placebo-controlled, double-blind Phase II clinical trial with bertilimumab in 90 patients for the treatment of active moderate-to-severe ulcerative colitis. Immune expects to report results from this trial in 2014.

The companies' collective oncology portfolios comprise Immune's NanomAbs<sup>®</sup>, a new generation of antibody drug conjugates, and EpiCept's vascular disruption agents. The combined company will continue efforts to secure a partner for EpiCept's Phase III clinical development candidate AmiKet™, for which efficacy has been demonstrated for the treatment of chemotherapy-induced neuropathic pain and post-herpetic neuralgia.

• 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 2011 EpiCept met with the U.S. Food and Drug Administration (FDA) and was granted permission by the FDA to initiate the Phase III clinical development of AmiKet™. Fast Track designation was granted in April 2012. 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. The FDA also agreed that a Special Protocol Assessment is available with respect to the protocol for the first Phase III trial in chemotherapy-induced peripheral neuropathy (CIPN). In May 2012 EpiCept received formal scientific advice from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) for the Phase III

clinical and nonclinical development and subsequent Marketing Authorization Approval (MAA) filing of AmiKet™ in the treatment of CIPN. In general, the CHMP's requirements are closely aligned with the guidance given EpiCept by the FDA.

- Crolibulin™ a vascular disruption agent (VDA) that has demonstrated potent anti-tumor activity in both preclinical and early clinical studies. In December 2010 the National Cancer Institute initiated a Phase Ib/II trial for crolibulin™ to assess safety and efficacy in combination with cisplatin in patients with anaplastic thyroid cancer. The Phase I safety portion of the trial has completed enrollment, and the Phase II randomized efficacy proof-of-concept study is expected to commence later this year.
- Azixa® a novel small molecule VDA and apoptosis inducer, Azixa® is a lipophilic compound that collects in the brain at significant concentrations. The compound was discovered by EpiCept and licensed to Myrexis, Inc. as part of an exclusive, worldwide development and commercialization agreement. In August 2012 Myrexis terminated its License and Collaboration Agreement with EpiCept relating to Azixa®. In December 2012 Myrexis licensed to EpiCept all of the Myrexis Technology (as defined in the License and Collaboration Agreement) in return for future milestone payments and a royalty on commercial sales. EpiCept is currently analyzing the Myrexis Technology and will determine its future plans for Azixa® in consultation with Immune. Azixa® has received orphan drug status in the U.S. for the treatment of glioblastoma multiforme (GBM).
- EP1013/F573 a di-peptide small-molecule compound with 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. In April 2012 EpiCept announced that new preclinical research for EP1013 (now renamed F573) concluded that the compound 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). EpiCept licensed rights to a series of patents for EP1013/F573 in China, Japan other key territories to GNI Group Ltd. to develop this drug for liver diseases.

#### **Additional Merger Information**

The terms of the merger agreement between EpiCept and Immune provide that, upon the closing of the transaction, EpiCept will issue shares of its common stock to Immune shareholders in exchange for all of the outstanding shares of Immune. EpiCept shareholders will retain approximately 19 percent ownership of the combined company and Immune shareholders will receive approximately 81 percent, calculated on an adjusted fully diluted basis, assuming the full drawdown of \$0.5 million in equity capital that is available from Immune pursuant to the Second Amendment to the Merger Agreement and Plan of Reorganization that was signed in February 2013. The proportionate ownership of the combined company by EpiCept and Immune shareholders is subject to further adjustment based upon the size of certain specified liabilities of EpiCept at the merger effective time, and initially excludes the exercise or conversion of certain EpiCept options and warrants whose exercise/conversion prices are significantly higher than the current trading price of EpiCept's common stock.

The combined company will be named Immune Pharmaceuticals Inc. and have dual headquarters in Herzliya-Pituach, Israel and in the New York City area, with research laboratories in Rehovot, Israel. Daniel Teper, PharmD, Chief Executive Officer of Immune Pharmaceuticals Ltd., will be the Chairman and CEO of the combined company. Dr. David Sidransky, Director of Head and Neck Research Division, Professor of Oncology at the Johns Hopkins School of Medicine, and a former Vice Chairman of the Board of Directors of ImClone Systems, will be the Vice Chairman of the Board of the combined company. The combined company plans to assume EpiCept's common stock listings on the OTCQX and on the NASDAQ OMX Stockholm Exchange.

## Financial and Operating Highlights

EpiCept's net loss for the fourth quarter of 2012 was \$0.9 million, or \$0.01 per share, compared with a net loss of \$3.5 million, or \$0.05 per share for the fourth quarter of 2011. The net loss for the full year 2012

was \$2.6 million, or \$0.07 per share, compared with a net loss of \$15.7 million, or \$0.23 per share, for the full year 2011.

#### Fourth Quarter 2012 vs. Fourth Quarter 2011

#### Revenue

The Company recognized revenue of \$0.1 million during the fourth quarter of 2012, a decrease of \$0.1 million compared with \$0.2 million in the fourth quarter of 2011. The decrease was primarily related to lower revenue recognition from upfront license fees and milestone payments received from the Company's strategic partners.

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

Cost of goods sold in the fourth quarters of 2012 and 2011 was \$6,000 and \$0.3 million, respectively. Cost of goods sold in the 2011 quarter consisted primarily of a \$0.3 million expense for Ceplene® inventory the Company believed would not be sold prior to reaching its product expiration date.

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

SG&A expense in the fourth quarter of 2012 decreased by 10%, or \$0.1 million, to \$0.9 million from \$1.0 million in the fourth quarter of 2011. The decrease was primarily related to lower salary-related expenses resulting from the departure of the Company's CEO in the third quarter of 2012.

#### Research and Development Expense

Research and development expense in the fourth quarter of 2012 decreased by 98%, or \$1.5 million, to \$38,000 from \$1.6 million in the fourth quarter of 2011. This decrease was primarily related to a \$0.7 million milestone payment that was recorded in 2006 and reversed in 2012 as the licensee failed to request payment of the milestone fee within the six year statute of limitations, lower clinical trial expenses in connection with the sale of EpiCept's rights to Ceplene® in Europe and certain Pacific Rim countries in June 2012 and lower salary-related expenses resulting from a reduction of staff in 2012.

#### Other Income (Expense)

Other income (expense) during the fourth quarters of 2012 and 2011 amounted to net income of \$22,000 and net expense of \$0.8 million, respectively. The primary component of other income in the fourth quarter of 2012 was a foreign exchange gain, partially offset by interest expense. The primary component of other expense in 2011 was interest expense on the Company's senior secured debt and foreign exchange loss.

#### Full Year 2012 vs. Full Year 2011

#### Revenue

During the years 2012 and 2011, the Company recognized revenue of \$7.8 million and \$0.9 million, respectively. Revenue in 2012 was primarily related to the sale of the Company's rights to Ceplene® to Meda AB for \$2.0 million, product revenues from the sale of Ceplene® and recognition of prior upfront licensing fees and milestone payments received from strategic alliances. As a result of the Company's termination of its commercialization agreement with Meda and its license and collaboration agreement with Myrexis, the Company recognized revenue from prior upfront licensing fees and milestone payments received from Meda and Myrexis of \$3.8 million and \$0.7 million in 2012 and 2011, respectively. Revenue in 2011 was primarily related to the recognition of deferred revenue from the Company's license

agreements with its partners, as well as to royalties with respect to certain technology and sales of Ceplene®.

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

Cost of goods sold in 2012 and 2011 was \$0.4 million and \$0.7 million, respectively, consisting primarily of costs related to the sale of Ceplene<sup>®</sup>, and a \$0.7 million expense in 2011 for Ceplene<sup>®</sup> inventory the Company believed would not be sold prior to reaching its product expiration date.

#### Selling, General and Administrative Expense

SG&A expense in 2012 decreased by approximately 28%, or \$1.9 million, to \$4.6 million from \$6.5 million in 2011. The decrease can be attributed to lower salary-related expenses, lower stock-based compensation expense, lower public reporting costs and lower investor relations expenses, as well as costs related to certain financing-related activities in 2011.

## Research and Development Expense

Research and development expense in 2012 decreased by approximately 57%, or \$4.5 million, to \$3.4 million from \$7.9 million in 2011. The decrease was primarily attributable to lower clinical trial expenses with the sale of Ceplene® to Meda in June 2012, lower salary-related expenses and lower patent maintenance fees.

## Other Income (Expense)

Other income (expense) during 2012 amounted to a net expense of \$2.0 million, compared with a net expense of \$1.6 million during 2011. The \$0.4 million increase was primarily related to a \$0.9 million warrant amendment expense, offset by a \$0.2 million foreign exchange gain in 2012, compared with a \$0.3 million foreign exchange loss in 2011.

# Liquidity

EpiCept had approximately \$0.2 million in cash and cash equivalents as of December 31, 2012. In addition, EpiCept's lender has restricted \$0.8 million of its cash and EpiCept is required to make monthly interest payments on its senior secured term loan. In February 2013 EpiCept entered into an amendment to the Merger Agreement and Plan of Reorganization with Immune that permits Immune to purchase new shares of EpiCept common stock directly from EpiCept at a purchase price of \$0.13 per share at any time and from time to time prior to the effective time of the merger. Any shares of EpiCept common stock sold to Immune in such a pre-merger investment will be cancelled at the effective time of the merger, but the relative post-closing ownership percentages in the combined company will be adjusted at the closing such that, for each \$100,000 invested by Immune in EpiCept pursuant to such a pre-merger investment (up to an aggregate of \$500,000), the post-closing ownership percentage of the pre-closing Immune stockholders in the combined company will be increased by an additional 0.7%. In February 2013, EpiCept received \$0.3 million in cash from Immune Pharmaceuticals Ltd. through the issuance of approximately 2.3 million shares of EpiCept common stock. The Company believes that its current cash plus cash available from Immune is sufficient to fund operations into the second quarter of 2013.

EpiCept anticipates the merger with Immune will close during the second quarter of 2013, subject to satisfaction of certain customary closing conditions. However, as additional funds will be required prior to the merger closing, EpiCept is considering various transactions to obtain additional cash resources to fund operations, including additional funding from Immune, the sale or licensing of assets and the sale of equity securities to third parties. If unable to complete such a transaction or otherwise obtain funding on a timely basis, EpiCept may be forced to further reduce expenses or curtail operations.

EpiCept's obligations under its outstanding loan with MidCap Financial LLC are expected to be assumed by the combined company upon closing. Currently, interest only is being paid on the loan on a monthly basis. EpiCept and Immune have agreed to indicative terms and conditions offered by MidCap Financial related to the loan's restructure upon the merger closing. Negotiations are currently ongoing regarding the treatment of the loan prior to the closing of the merger.

EpiCept also announced today that in its Annual Report on Form 10-K for the year ended December 31, 2012, the Company's independent registered public accounting firm is expected to express an unqualified opinion on the December 31, 2012 consolidated financial statements and will include an explanatory paragraph expressing substantial doubt about the Company's ability to continue as a going concern. EpiCept expects to release its interim results for the period ending March 31, 2013 on or about May 10, 2013.

#### **Additional Information**

In connection with the proposed merger transaction, EpiCept will file a proxy statement with the U.S. Securities and Exchange Commission (SEC) seeking appropriate stockholder approval. STOCKHOLDERS OF EPICEPT AND OTHER INVESTORS ARE URGED TO READ THE PROXY STATEMENT (INCLUDING ANY AMENDMENTS OR SUPPLEMENTS TO THE PROXY STATEMENT) REGARDING THE PROPOSED TRANSACTION WHEN IT BECOMES AVAILABLE BECAUSE IT WILL CONTAIN IMPORTANT INFORMATION. EpiCept's stockholders will be able to obtain a copy of the proxy statement, as well as other filings containing information about Immune and EpiCept, without charge, at the SEC's Internet site (<a href="https://www.sec.gov">www.sec.gov</a>). Copies of the proxy statement and the filings with the SEC that will be incorporated by reference in the proxy statement can also be obtained, without charge, by directing a request to EpiCept Corporation, 777 Old Saw Mill River Rd, Tarrytown, NY 10591, Attention: Investor Relations, Telephone: (914) 606-3500.

## Participants in the Solicitation

EpiCept and its directors and executive officers and Immune and its directors and executive officers may be deemed to be participants in the solicitation of proxies from the stockholders of EpiCept in connection with the proposed transaction. Information regarding the special interests of these directors and executive officers in the merger transaction will be included in the proxy statement of EpiCept referred to above. Additional information regarding the directors and executive officers of EpiCept is also included in EpiCept's proxy statement for its 2011 Annual Meeting of Stockholders, which was filed with the SEC on April 28, 2011. Additional information regarding the directors and executive officers of EpiCept is also included in EpiCept's registration statement Post-Effective Amendment No. 1 to Form S-3 on Form S-1, which was filed with the SEC on April 26, 2012. These documents are available free of charge at the SEC's web site (<a href="https://www.sec.gov">www.sec.gov</a>) and from Investor Relations at EpiCept at the address described above.

This communication shall not constitute an offer to sell or the solicitation of an offer to buy any securities, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. No offering of securities shall be made except by means of a prospectus meeting the requirements of Section 10 of the Securities Act of 1933, as amended (the "Act"). The securities issued in exchange for all of the outstanding shares of Immune will not be and have not been registered under the Act and may not be offered or sold in the United States absent registration or an applicable exception from registration requirements.

The merger agreement and any accompanying issuance of shares by Immune Pharmaceuticals are not, under any circumstances, to be construed as an advertisement or a public offering of securities in Israel. Any public offer or sale of securities in Israel may be made only in accordance with the Israeli Securities Act-1968 (which requires, inter alia, the filing of a prospectus in Israel or an exemption therefrom).

#### **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™, 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®, 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® in Europe and certain Pacific Rim countries and a portion of its remaining Ceplene® inventory to Meda AB in June 2012. Ceplene® is licensed to MegaPharm Ltd. to market and sell in Israel and EpiCept has retained its rights to Ceplene® 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 inhouse technology and have been shown to act as vascular disruption agents in a variety of solid tumors.

#### **About Immune Pharmaceuticals Ltd.**

Immune Pharmaceuticals Ltd. is an Israel and U.S.-based biopharmaceutical company focused on the development of next-generation antibody therapeutics to address unmet medical needs in the treatment of inflammatory diseases and cancer. Immune licensed worldwide rights for systemic indications of bertilimumab from iCo Therapeutics (TSX: ICO) in June 2011, while iCo retained rights to all ophthalmic indications. iCo originally licensed exclusive worldwide rights to bertilimumab in 2006 from MedImmune Limited (formerly known as Cambridge Antibody Technology Limited), the global biologics unit of AstraZeneca. Additionally, Immune has licensed from Yissum, the Technology Transfer Company of the Hebrew University of Jerusalem, injectable applications of the antibody nanoparticle conjugate technology (NanomAbs®) developed by Prof. Shimon Benita. For more information, visit the Immune website at <a href="https://www.immunepharmaceuticals.com">www.immunepharmaceuticals.com</a>.

#### **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. You are urged to consider statements that include the words "may," "will," "would," "could," "should," "believes," "estimates," "projects," "potential," "expects," "plans," "anticipates," "intends," "continues," "forecast," "designed," "goal" or the negative of those words or other comparable words to be uncertain and forward-looking. Such forward-looking statements include statements that 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 risk that we may be unable to complete the proposed merger transaction with Immune Pharmaceuticals; 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 clinical trials for AmiKet™ or crolibulin™ will not be successful; the risk that AmiKet™, Azixa® or crolibulin™ 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™ on attractive terms, a timely basis or at all; the risk that Ceplene® will not receive regulatory approval or marketing authorization in the United States or Canada; the risk that Ceplene® 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 <a href="www.sec.gov">www.sec.gov</a> or at <a href="www.sec.gov">www.epicept.com</a>. 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 Sheets Data (in \$000s)

	December 31,				
		<u>2012</u>	<u>2011</u>		
Cash and cash equivalents	\$	172	\$	6,378	
Inventory		_		360	
Property and equipment, net		56		120	
Total assets	\$	1,328	\$	7,521	
Accounts payable and other accrued liabilities	\$	3,512	\$	3,333	
Deferred revenue		7,810		12,947	
Notes and loans payable		3,975		8,022	
Total stockholders' deficit	(	13,969)	(	(17,146)	
Total liabilities and stockholders' deficit	\$	1,328	\$	7,521	

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

		nths Ended lber 31,		Year Ended December 31,			
	<u>2012</u>	<u>2011</u>	<u>2012</u>	<u>2011</u>			
Net product sales	_	4	583	39			
Licensing and other revenue	91	203	7,221	905			
Total revenue \$	91	\$ 207	\$ 7,804	\$ 944			
Costs and expenses:							
Cost of goods sold	7	281	403	692			
Selling, general and administrative	940	1,039	4,607	6,452			
Research and development	38	1,561	3,400	7,853			
Total costs and expenses	985	2,881	8,410	14,997			
Loss from operations	(894)	(2,674)	(606)	(14,053)			
Other income (expense):							
Interest income		2	4	12			
Foreign exchange gain (loss)	223	(378)	166	(340)			
Interest expense	(201)	(401)	(1,199)	(1,271)			
Warrant amendment expense	_		(936)				
Other income (expense), net	22	(777)	(1,965)	(1,599)			

Net loss before income taxes Income taxes		(872) —		(3,451)		<b>(2,571)</b> (2)	<b>(15,652)</b> (4)
Net loss	\$	(872)	\$	(3,451)	\$	(2,573)	\$ (15,656)
Deemed dividends on convertible preferred stock		_	_	_	_	(3,550)	_
Net loss	\$	(872)	\$	(3,451)	\$	6 (6,123)	\$ (15,656)
Basic and diluted loss per common share	\$	(0.01)	\$	(0.05)	9	6 (0.07)	\$ (0.23)
Weighted average common shares outstanding	_	92,297,822	_	71,003,667	-	84,458,376	68,313,381

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

	Ye	ar Ended <u>2012</u>	Dec	December 31, <u>2011</u>			
Net cash used in operating activities	\$	(5,339)	\$	(14,002)			
Net cash (used in) provided by investing activities		(839)		97			
Net cash (used in) provided by financing activities		(13)		17,840			
Effect of exchange rate changes on cash		(15)		8			
Net increase (decrease) in cash and cash equivalents		(6,206)		3,943			
Cash and cash equivalents at beginning of year		6,378		2,435			
Cash and cash equivalents at end of year	\$	172	\$	6,378			

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

	Yea	ar Ended [ 2012	December 31, 2011			
Stockholders' deficit at beginning of year	\$	(17,146)	\$	(14,135)		
Net loss for the period Stock-based compensation expense Foreign currency translation adjustment Share and warrant issuance Exercise of warrants Warrant issuance		(2,573) 692 (179) 2,833 1,468 936		(15,656) 930 299 10,872 — 544		
Stockholders' deficit at end of year	\$	(13,969)	\$	(17,146)		

As of February 28, 2013, EpiCept had 112,215,568 shares outstanding.

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