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CPEX Pharmaceuticals Reports 2009 Fourth-Quarter and Year-End Financial Results

Exeter, NH, March 3, 2010 – CPEX Pharmaceuticals, Inc. (NASDAQ: CPEX) today reported financial results for the fourth quarter and year ended December 31, 2009. For the quarter CPEX reported revenues of \$5.2 million and a net loss of \$498,000. For the year CPEX reported revenues of \$18.7 million and a net loss of \$3.0 million.

Operating expenses for the year ended December 31, 2008 include a \$1.2 million non-cash charge resulting from the modification of equity awards and \$2.5 million of expenses related to the spin-off from Bentley Pharmaceuticals on June 30, 2008.

Fourth-Quarter Highlights

For the fourth quarter of 2009 compared to the fourth quarter of 2008:

- Revenues increased 23% to \$5.2 million from \$4.2 million.
- Operating expenses increased 45% to \$5.8 million from \$4.0 million.
- Net loss was \$498,000, or \$0.20 per share, compared to net income of \$292,000, or \$0.12 per share.

The growth in revenues for the fourth quarter of 2009 was due to increased royalties on sales of Testim[®]. This growth is due to a reported 13.2% increase in prescriptions for Testim during the fourth quarter of 2009 compared to the same period in 2008.

General and administrative expenses for the fourth quarter of 2009 increased \$1.1 million compared to the fourth quarter of 2008 due to \$1.2 million in costs relating to the Upsher-Smith litigation. Research and development expenses for the fourth quarter of 2009 increased \$627,000 compared to the fourth quarter of 2008 largely due to a \$489,000 increase in expenses related to the Nasulin clinical program. Research and development expenses are expected to vary from period to period, primarily due to the number, size and recruitment levels of clinical trials in any given reporting period.

Year-to-Date Highlights

For the year ended December 31, 2009 compared to the comparable period in 2008:

- Revenues increased 20% to \$18.7 million from \$15.6 million.
- Operating expenses increased 16% to \$21.9 million from \$18.8 million.
- Net loss increased to \$3.0 million, or \$1.21 per share, from \$2.9 million, or \$1.25 per share.

The increase in revenues for the twelve months ended December 31, 2009 was due to increased royalties on sales of Testim[®]. For the year ended December 31, 2009, Testim prescriptions were reported to have grown 14.9% compared to the same period in 2008. General and administrative expenses increased \$2.4 million in the year ended December 31, 2009 compared to the same period in 2008. The increase was primarily due to increased litigation costs of \$2.8 million partially offset by a \$674,000 decrease in non-cash share-based compensation expense. Research and development expenses increased \$3.2 million during the year ended December 31, 2009 compared to 2008 due to a \$3.7 million increase in clinical trial expenses, primarily related to the Nasulin clinical program, which were partially offset by lower non-cash share-based compensation expense of \$494,000.

On June 30, 2008, CPEX had approximately 2,274,000 common shares outstanding after the spin-off. The same number of shares is being used for the basic and diluted loss per share computation for all periods presented prior to June 30, 2008 because no CPEX equity awards were outstanding prior to the spin-off.

As of December 31, 2009, CPEX had unrestricted cash of approximately \$13.7 million, working capital of \$16.6 million and no debt.

Business Update

Ongoing Clinical Trials: CPEX's intranasal insulin product candidate for the treatment of hyperglycemia in patients with Type 1 and Type 2 diabetes, Nasulin, is continuing in clinical trials evaluating the efficacy and safety profile of the product. CPEX has completed enrollment in its Phase 2a study designed to assess the efficacy and safety of Nasulin versus placebo over a 6-week treatment period. This study was conducted at multiple sites in the U.S. and randomized 94 patients. Data analysis is ongoing and preliminary results are expected this month. Earlier clinical studies of Nasulin indicated that CPEX's intranasal insulin candidate achieved a faster time to peak plasma insulin levels when compared to other approved rapid-acting insulin therapies, thereby more closely mimicking the natural response of the pancreas to meals.

Patent Infringement Lawsuit Update: CPEX and Auxilium Pharmaceuticals, Inc. continue to vigorously pursue their lawsuit against Upsher-Smith for infringement of CPEX's patent that covers Testim. In August 2009, the U.S. Food and Drug Administration (FDA) responded to a Citizen Petition filed by Auxilium. The FDA agreed with some of the statements made in the Citizen Petition regarding the testing required for generic versions of Testim, while disagreeing with other statements. While the FDA did not comment upon any particular filing, the agency stated that: "The practical effect of this determination is that any application for a testosterone gel product that has different penetration enhancers than the reference listed drug cannot be submitted as an ANDA [(i.e., an abbreviated new drug application)] and, instead, will have to be submitted as an NDA under section 505(b) of the Act." (FDA's August 26, 2009, Response to Auxilium's Citizen Petition)

Partnering Update: Serenity Pharmaceuticals, CPEX's licensing and development partner, continues to recruit patients in multiple Phase 3 clinical trials of their undisclosed urology drug, which is delivered

using CPEX's intranasal technology for the treatment of nocturia. These randomized, double blind, placebo controlled studies are being conducted at multiple sites in the United States.

New Chief Scientific Officer: On February 1, 2010, CPEX announced the appointment of Nils Bergenhem, Ph.D. as its Chief Scientific Officer. Prior to joining CPEX, Dr. Bergenhem served as Chief Scientific Officer at Escoublac, Inc., the first biotechnology company in the Biogen Idec Innovations Incubator, where he was responsible for development and execution of the research plan for human osteocalcin in metabolic disease, Type 2 diabetes and obesity. Dr. Bergenhem succeeds Fred Feldman, Ph.D., who is retiring after a 35 year career in research and drug development.

Management Comments

“We are pleased with our progress during 2009, our first full year as a stand-alone company” stated John A. Sedor, CPEX President and Chief Executive Officer. “We are enthusiastic about the recent completion of enrollment in our Phase 2a study of Nasulin and we look forward to finalizing our analysis and announcing the results. Royalties on sales of Testim are continuing to grow, and we are encouraged by the continued advancement of Serenity's urology program and the pipeline opportunities that lie ahead.”

About CPEX Pharmaceuticals

CPEX Pharmaceuticals, Inc. is an emerging specialty pharmaceutical company focused on the development, licensing and commercialization of pharmaceutical products utilizing CPEX's validated drug delivery platform technology. CPEX has U.S. and international patents and other proprietary rights to technology that facilitates the absorption of drugs. CPEX has licensed applications of its proprietary CPE-215[®] drug delivery technology to Auxilium Pharmaceuticals, Inc., which launched Testim[®], a topical testosterone gel, in 2003. CPEX also is developing a proprietary intranasal insulin product candidate, Nasulin[™], which is currently in Phase 2 clinical trials. CPEX maintains its headquarters in Exeter, NH. For more information about CPEX, please visit www.cpexpharm.com.

CPEX began operating as an independent publicly traded company after its spin-off from Bentley Pharmaceuticals, Inc. (“Bentley”) on June 30, 2008. The results of operations for the three and twelve months ended December 31, 2009, the three months ended December 31, 2008 and the balance sheets as of December 31, 2009 and 2008 represent stand-alone financial information of CPEX. The financial results reported for the twelve months ended December 31, 2008 (which include six months before the spin-off) include costs associated with the spin-off transaction and other allocated expenses of Bentley, the amount of which may differ from the costs associated with operating as an independent public company. Therefore, the results for the twelve months ended December 31, 2008 are not indicative of the results that might have occurred if CPEX had operated as an independent public company during the entire period.

Safe Harbor Statement under the U.S. Private Securities Litigation Reform Act of 1995:

This press release contains forward-looking statements, including, without limitation, statements regarding the potential activity profile of Nasulin, the prospects for CPEX's development programs for Nasulin and the timeframe for announcement of results of its Phase 2a study, the prospects for Serenity's Phase 3 clinical trials for its undisclosed urology drug and the prospects for growing sales of Testim and the CPEX pipeline. These forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from future results expressed or implied by such statements. Factors that may cause such differences include, but are not limited to, risks associated with the following: clinical trials may not demonstrate the efficacy and safety of CPEX product candidates, regulatory approvals may be delayed or not obtained at all, competition from other

products and from the ANDA application of Upsher-Smith, the unpredictability of patent protection, CPEX's dependence on obtaining agreements with other parties to conduct clinical trials and commercialize its product candidates that use its drug delivery technology, CPEX's products may not achieve market acceptance or favorable reimbursement rates from health insurers, intellectual property litigation, and other uncertainties detailed under "Risk Factors" in CPEX's Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 25, 2009. CPEX cautions investors not to place undue reliance on the forward-looking statements contained in this release. These statements speak only as of the date of this document, and CPEX undertakes no obligation to update or revise the statements, except as may be required by law.

CPEX Pharmaceuticals, Inc. and Subsidiaries
Unaudited Condensed Consolidated and Combined Statements of Operations

(in thousands, except per share data)

	For the Three Months Ended December 31,		For the Twelve Months Ended December 31,	
	<u>2009</u>	<u>2008</u>	<u>2009</u>	<u>2008</u>
Royalties and other revenue	\$ 5,223	\$ 4,230	\$ 18,658	\$ 15,574
Operating expenses:				
General and administrative	2,592	1,471	8,867	6,493
Research and development	2,968	2,341	12,291	9,119
Separation costs	—	—	—	2,502
Depreciation and amortization	<u>194</u>	<u>167</u>	<u>699</u>	<u>682</u>
Total operating expenses	<u>5,754</u>	<u>3,979</u>	<u>21,857</u>	<u>18,796</u>
(Loss)income from operations	<u>(531)</u>	<u>251</u>	<u>(3,199)</u>	<u>(3,222)</u>
Other income (expenses):				
Interest income	34	42	162	312
Interest expense	<u>(1)</u>	<u>(1)</u>	<u>(3)</u>	<u>(5)</u>
Net (loss) income	<u>\$ (498)</u>	<u>\$ 292</u>	<u>\$ (3,040)</u>	<u>\$ (2,915)</u>
Net (loss) income per common share:				
Basic and diluted	<u>\$ (0.20)</u>	<u>\$ 0.12</u>	<u>\$ (1.21)</u>	<u>\$ (1.25)</u>
Weighted average common shares outstanding:				
Basic	2,535	2,466	2,511	2,338
Diluted	<u>2,535</u>	<u>2,485</u>	<u>2,511</u>	<u>2,338</u>

CPEX Pharmaceuticals, Inc. and Subsidiaries
Unaudited Condensed Consolidated Balance Sheets

(in thousands, except per share data)

	<u>December 31,</u> <u>2009</u>	<u>December 31,</u> <u>2008</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,695	\$ 15,211
Receivables	5,289	4,445
Prepaid expenses and other	<u>593</u>	<u>583</u>
Total current assets	<u>19,577</u>	<u>20,239</u>
Non-current assets:		
Fixed assets, net	2,938	2,832
Intangible assets, net	2,211	2,394
Restricted cash	1,000	1,000
Other	<u>317</u>	<u>8</u>
Total non-current assets	<u>6,466</u>	<u>6,234</u>
Total assets	<u>\$ 26,043</u>	<u>\$ 26,473</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,374	\$ 1,096
Accrued expenses	<u>1,633</u>	<u>1,534</u>
Total current liabilities	<u>3,007</u>	<u>2,630</u>
Commitments and contingencies		
Stockholders' equity:		
Series A Preferred stock, \$0.01 par value, authorized 1,000 shares, issued and outstanding, none	—	—
Common stock, \$0.01 par value, authorized 35,000 shares, issued and outstanding, 2,537 shares and 2,484, respectively	25	25
Additional paid-in capital	26,765	24,532
Accumulated deficit	<u>(3,754)</u>	<u>(714)</u>
Total stockholders' equity	<u>23,036</u>	<u>23,843</u>
Total liabilities and stockholders' equity	<u>\$ 26,043</u>	<u>\$ 26,473</u>

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