



## **FOR IMMEDIATE RELEASE**

### **Contacts:**

Bob Hebert  
Chief Financial Officer  
CPEX Pharmaceuticals, Inc.  
603.658.6100  
[rhebert@cpepharm.com](mailto:rhebert@cpepharm.com)

Laura Okpala  
The Trout Group  
617.583.1306  
[lokpala@troutgroup.com](mailto:lokpala@troutgroup.com)

## **CPEX Pharmaceuticals Reports 2008 Fourth Quarter and Year-End Financial Results**

**Exeter, NH, March 5, 2009** – CPEX Pharmaceuticals, Inc. (NASDAQ: CPEX) today reported its financial results for the fourth quarter and year ended December 31, 2008. For the quarter the Company reported revenues of \$4.2 million and net income of \$292,000. For the year the Company reported revenues of \$15.6 million and a net loss of \$2.9 million.

CPEX began operating as an independent publicly traded company after its spin-off from Bentley Pharmaceuticals, Inc. on June 30, 2008. The financial results reported for the years ended December 31, 2008 and 2007 and three months ended December 31, 2007 include costs associated with the spin-off transaction and other allocated expenses of Bentley. Therefore, the results for those periods are not indicative of the results that might have occurred if CPEX had operated as an independent public company for those periods. The results of operations for the three months ended December 31, 2008 and balance sheet as of December 31, 2008 represent stand-alone financial information of CPEX and its subsidiaries.

### **Fourth-Quarter Highlights**

For the fourth quarter of 2008 compared to the fourth quarter of 2007:

- Revenues increased 31% to \$4.2 million from \$3.2 million.
- Operating expenses decreased 7% to \$4.0 million from \$4.3 million.
- Net income was \$292,000, or \$0.12 per share, compared to a net loss of \$886,000 or a loss of \$0.39 per share.

The increase in revenues for the fourth quarter of 2008 was primarily due to higher royalties on sales of Testim<sup>®</sup> in the quarter. This growth is due to a reported 24% increase in prescriptions for Testim during the fourth quarter of 2008 compared to the same period in 2007. In addition, it is reported that Testim's market share of the testosterone replacement gel market in December 2008 increased to 22.3% versus 21.5% in December 2007. The decrease in operating expenses during the fourth quarter of 2008 was primarily attributable to separation costs in 2007 of \$433,000 related to

the spin-off from Bentley mentioned above. No additional separation costs have been incurred by CPEX subsequent to its spin-off from Bentley in June 2008.

General and administrative and research and development expenses for the fourth quarter of 2008 were comparable to the same period in 2007. 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 period. Due to planned increases in spending on research and development, CPEX does not expect to report net income in subsequent quarters during 2009.

The diluted weighted average common shares outstanding for the three month period ended December 31, 2008 assumes that 2,274,000 shares were outstanding for the first six months of 2008, which is the number of CPEX shares distributed to Bentley stockholders on June 30, 2008. The same number of shares is being used for the loss per share computation for all prior periods because no CPEX equity awards were outstanding prior to the spin-off.

### **Year-to-Date Highlights**

For the year ended December 31, 2008 compared to the comparable period in 2007;

- Revenues increased 40% to \$15.6 million from \$11.1 million.
- Operating expenses increased 13% to \$18.8 million from \$16.6 million.
- Net loss decreased to \$2.9 million, or \$1.25 per share, from \$4.9 million, or \$2.17 per share.

The increase in revenues for the year ended December 31, 2008 was primarily due to growth in royalties on sales of Testim explained above. For the year ended December 31, 2008, Testim prescriptions were reported to have grown 26.5% compared to the same period in 2007. Revenues in 2008 also included approximately \$513,000 in funded research and development activities. The increase in operating expenses in 2008 is primarily due to charges related to the spin-off from Bentley, including an increase in separation costs of \$1.5 million and non-cash, share-based compensation charges of \$1.2 million.

As of December 31, 2008, CPEX had unrestricted cash of approximately \$15.2 million, working capital of \$17.6 million and no debt.

### **Business Update**

**Paragraph IV Certification Notice:** As previously announced, in October 2008 CPEX received a notice from Upsher-Smith Laboratories advising of the filing by Upsher-Smith of an Abbreviated New Drug Application (ANDA) containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for testosterone gel. This notice states that Upsher-Smith Laboratories does not believe that their product infringes our patent which covers Testim. On December 4, 2008, CPEX and Auxilium Pharmaceuticals, Inc (NASDAQ:AUXL) filed a lawsuit against Upsher-Smith for infringement of CPEX's U.S. patent No. 7,320,968, which covers Testim<sup>®</sup> 1% testosterone gel. CPEX filed this lawsuit in the United States District Court for the District of Delaware under the Hatch –Waxman Act in response to this notice.

Under the Hatch-Waxman Act, final FDA approval of Upsher-Smith's proposed generic product will be stayed until the earlier of 30 months or resolution of the patent infringement lawsuit. Should Upsher-Smith receive a tentative approval of its generic version of Testim from the FDA, it cannot lawfully launch its generic version of Testim in the U.S. before the earlier of the expiration of the currently pending 30-month stay or a district court decision in its favor. Upsher-Smith will also not

be able to lawfully launch a generic version of Testim in the U.S. without the necessary final approval from the FDA.

**Continued Progress with Serenity Pharmaceuticals Collaboration:** On February 26, 2009 CPEX announced that its development and commercialization partner, Serenity Pharmaceuticals, completed a Phase 2a clinical study of its intranasal drug candidate for an undisclosed urology indication which is delivered using CPEX's patented platform technology. During this study, 41 out of the 43 patients treated showed a positive response to treatment. Serenity has also completed an end-of-Phase-2 meeting with the FDA.

**Nasulin™ Phase 2 Clinical Trials Ongoing:** CPEX's intranasal insulin product candidate, Nasulin, is continuing extensive clinical trials evaluating the safety and efficacy profile of the product in patients with Type 1 and Type 2 diabetes. On February 24, 2009, CPEX announced the initiation of a Phase 2a, double-blind, placebo-controlled study designed to assess the efficacy and safety of Nasulin versus placebo over a 6-week treatment period. This study is being conducted at multiple centers in the U.S. Prior Phase 1 and 2 trials in patients with Type 1 or 2 diabetes as well as healthy volunteers have indicated that Nasulin appears to have an ultra-rapid time/action profile which has the potential to more closely mimic the body's natural insulin response to meals.

**New Chief Medical Officer:** On February 2, 2009, CPEX announced the appointment of Lance Berman, M.D. as its Chief Medical Officer. Prior to joining CPEX, Dr. Berman served as Senior Medical Director and Global Medical Team Leader at Pfizer, responsible for the strategic development and evolution of its worldwide diabetes portfolio. Dr. Berman succeeds Robert M. Stote M.D., who had been serving as the CMO of CPEX since its spin-off from Bentley in June of 2008.

## Management Comments

“2008 has been a breakout year for CPEX, one in which we have put into place a strong foundation to build upon,” commented John A. Sedor, president and chief executive officer. “Our core drug delivery technology has a validated marketed product in Testim® in addition to two other drug candidates in clinical development, including an undisclosed urology drug candidate partnered with Serenity Pharmaceuticals and our proprietary intranasal insulin candidate Nasulin®. We believe we are creating a balanced portfolio of pipeline candidates stemming from our widely applicable CPE-215® platform and we are well-positioned to continue to unlock the unrealized potential of the Company.”

## About CPEX Pharmaceuticals

CPEX Pharmaceuticals, Inc. (NASDAQ: CPEX) 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 technologies that facilitate 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 an intranasal insulin product candidate, Nasulin, which is in Phase 2 clinical trials. CPEX maintains its headquarters in Exeter, NH. For more information about CPEX, please visit [www.cpexpharm.com](http://www.cpexpharm.com).

## **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 prospects for further applications of CPEX's drug delivery platform technology, future prospects and opportunities for growth of CPEX, the prospects for CPEX's development activities and its portfolio of pipeline candidates, including Nasulin. 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 Registration Statement on Form 10 dated June 17, 2008 in connection with the distribution of CPEX's common stock to stockholders of Bentley Pharmaceuticals, Inc. 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 Combined Statements of Operations**

*(in thousands, except per share data)*

	<b>For the Three Months Ended December 31,</b>		<b>For the Twelve Months Ended December 31,</b>	
	<u>2008</u>	<u>2007</u>	<u>2008</u>	<u>2007</u>
Royalties and other revenue	\$ 4,230	\$ 3,240	\$ 15,574	\$ 11,127
Operating expenses:				
General and administrative	1,471	1,331	6,493	5,206
Research and development	2,341	2,378	9,119	9,646
Separation costs	—	433	2,502	1,010
Depreciation and amortization	<u>167</u>	<u>174</u>	<u>682</u>	<u>752</u>
Total operating expenses	<u>3,979</u>	<u>4,316</u>	<u>18,796</u>	<u>16,614</u>
Income/(loss) from operations	<u>251</u>	<u>(1,076)</u>	<u>(3,222)</u>	<u>(5,487)</u>
Other income (expenses):				
Interest income	42	208	312	591
Interest expense	(1)	(1)	(5)	(10)
Other, net	<u>—</u>	<u>(17)</u>	<u>—</u>	<u>(22)</u>
Net income/(loss)	<u>\$ 292</u>	<u>\$ (886)</u>	<u>\$ (2,915)</u>	<u>\$ (4,928)</u>
Net income/(loss) per common share:				
Basic and Diluted	<u>\$ 0.12</u>	<u>\$ (0.39)</u>	<u>\$ (1.25)</u>	<u>\$ (2.17)</u>
Weighted average common shares outstanding:				
Basic	2,466	2,274	2,338	2,274
Diluted	<u>2,485</u>	<u>2,274</u>	<u>2,338</u>	<u>2,274</u>

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

*(in thousands, except per share data)*

	<u>December 31,</u> <u>2008</u>	<u>December 31,</u> <u>2007</u>
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 15,211	\$ 21,659
Receivables	4,445	3,245
Prepaid expenses and other	<u>583</u>	<u>707</u>
Total current assets	<u>20,239</u>	<u>25,611</u>
Non-current assets:		
Fixed assets, net	2,832	2,800
Intangible assets, net	2,394	2,942
Restricted cash	1,000	1,000
Other	<u>8</u>	<u>44</u>
Total non-current assets	<u>6,234</u>	<u>6,786</u>
Total assets	<u>\$ 26,473</u>	<u>\$ 32,397</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 1,096	\$ 974
Accrued expenses	1,534	2,247
Other	<u>—</u>	<u>25</u>
Total current liabilities	<u>2,630</u>	<u>3,246</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, 2,483 shares	25	—
Additional paid-in capital	24,532	—
Bentley Pharmaceuticals, Inc. net investment	—	29,151
Accumulated deficit	<u>(714)</u>	<u>—</u>
Total stockholders' equity	<u>23,843</u>	<u>29,151</u>
Total liabilities and stockholders' equity	<u>\$ 26,473</u>	<u>\$ 32,397</u>

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