



## **Auxilium Pharmaceuticals, Inc. and CPEX Pharmaceuticals, Inc. File Lawsuit against Upsher-Smith Laboratories, Inc. for Infringement of Testim<sup>®</sup> Patent**

**MALVERN, PA and EXETER, NH (Dec. 4, 2008)** – Auxilium Pharmaceuticals, Inc. (NASDAQ: AUXL) and CPEX Pharmaceuticals, Inc. (NASDAQ:CPEX) announced today that they have filed a lawsuit against Upsher-Smith Laboratories, Inc. (Upsher-Smith) for infringement of CPEX’s U.S. Patent No. 7,320,968 (“the ’968 Patent”), which covers Testim<sup>®</sup>, 1% testosterone gel. The lawsuit was filed in the United States District Court for the District of Delaware.

The Companies filed this lawsuit under the Hatch-Waxman Act in response to the notice from Upsher-Smith of its filing of an Abbreviated New Drug Application (ANDA) with the U.S. Food and Drug Administration (FDA) containing a Paragraph IV certification under 21 U.S.C. Section 355(j) for testosterone gel. The Paragraph IV certification notice states that Upsher-Smith does not believe that the testosterone gel product for which it is seeking approval infringes the ’968 patent and that it would seek to market its generic product before the expiration of the ’968 patent. The ’968 Patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the U.S. FDA, and will expire in January 2025. Auxilium and CPEX are committed to protecting their intellectual property rights.

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.

### **About Testim**

Testim is a novel, topical gel formulation that normalizes low levels of testosterone in men with hypogonadism, a condition that occurs when a man’s body does not produce adequate amounts of testosterone. Testim was developed by Auxilium using a proprietary technology licensed from CPEX and was launched in the U.S. in the first quarter of 2003. Auxilium received its first European regulatory approval for Testim in the UK in 2003 and currently has regulatory approval in 15 countries in Europe.

### **About Hypogonadism**

A 2006 study that was published in *The International Journal of Clinical Practice* showed 39% of men over 45 years of age have low testosterone (total testosterone levels below 300 ng / dL). Hypogonadism is defined as reduced or absent secretion of testosterone which can lead to symptoms such as loss or decline of libido, decrease in energy, reduced muscle mass, an increase in abdominal fat, decreased sexual function, anemia, fatigue, depression, irritability, poor concentration, and reduced bone density that may result in an increased risk of osteoporosis. Auxilium research estimates that approximately 10% of men

with hypogonadism currently receive testosterone replacement therapy and that this low diagnosis rate stems primarily from low patient and physician awareness of the symptoms, treatment options and monitoring requirements

### **About Auxilium**

Auxilium Pharmaceuticals, Inc. is a specialty biopharmaceutical company with a focus on developing and marketing to urologists, endocrinologists, orthopedists and select primary care physicians. Auxilium markets Testim® 1%, a topical testosterone gel, for the treatment of hypogonadism through its approximately 190-person sales and marketing team. Auxilium has five projects in clinical development. XIAFLEX™ (clostridial collagenase for injection), formerly referred to as AA4500, is in phase III of development for the treatment of Dupuytren's contracture and is in phase II of development for the treatment of Peyronie's disease and Frozen Shoulder syndrome (Adhesive Capsulitis). Auxilium's transmucosal film product candidate for the treatment of overactive bladder (AA4010) is in phase I of development. The Company is currently seeking a partner to further develop this product candidate. Auxilium also has one pain product (fentanyl) using its transmucosal film delivery system in phase I of development. Auxilium has rights to seven additional pain products and products for hormone replacement and urologic disease using its transmucosal film delivery system. Auxilium also has options to all indications using XIAFLEX for non-topical formulations. For additional information, visit <http://www.auxilium.com>.

### **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 II clinical trials. CPEX maintains its headquarters in Exeter, NH. For more information about CPEX, please visit [www.cpepharm.com](http://www.cpepharm.com).

### **SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995**

#### ***Auxilium***

This press release contains "forward-looking statements" within the meaning of the provisions of The Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding: the number of men with hypogonadism currently receiving testosterone replacement therapy, reasons for the low diagnosis rate of hypogonadism; Auxilium's commitment to protecting its intellectual property rights; and all others statements containing projections, statements of future performance or expectations, or statements of plans or objectives for future operations (including statements of assumption underlying or relating to any of the foregoing). 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: the interpretation of market research, intellectual property litigation, the unpredictability of patent protection, competition from other products, and other risks and uncertainties detailed under "Risk Factors" in Auxilium's Annual Report on Form 10-K for the fiscal year ended December 31, 2007 and in Auxilium's Quarterly Report on Form 10-Q for the period ended September 30, 2008 which are on file with the Securities and Exchange Commission. Given these risks and

uncertainties, any or all of the forward-looking statements contained in this press release may prove to be incorrect. Therefore, you should not rely on any such factors or forward-looking statements. Forward-looking statements contained in this press release speak only as of the date of this document, and Auxilium undertakes no obligation to update or revise such statements.

Auxilium disclaims responsibility for statements above in “About CPEX Pharmaceuticals”, which were provided by CPEX for inclusion in this press release.

***CPEX***

This press release contains forward-looking statements, including, without limitation, statements regarding the legal and regulatory options available to defend U.S. Patent No. 7,320,968 and Testim and CPEX’s intentions regarding such options. 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: intellectual property litigation, the unpredictability of patent protection, competition from other products, 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 disclaims responsibility for statements above in “About Auxilium”, which were provided by Auxilium for inclusion in this release.

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