

SECURITIES AND EXCHANGE COMMISSION

FORM 8-K

Current report filing

Filing Date: **2013-01-28** | Period of Report: **2013-01-28**
SEC Accession No. [0001104659-13-005210](#)

([HTML Version](#) on [secdatabase.com](#))

FILER

AUXILIUM PHARMACEUTICALS INC

CIK: **1182129** | IRS No.: **233016883** | State of Incorporation: **DE** | Fiscal Year End: **1231**
Type: **8-K** | Act: **34** | File No.: **000-50855** | Film No.: **13552679**
SIC: **2834** Pharmaceutical preparations

Mailing Address

640 LEE ROAD
CHESTERBROOK PA 19087

Business Address

640 LEE ROAD
CHESTERBROOK PA 19087
484 321 5900

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of report (Date of earliest event reported): **January 28, 2013**

Auxilium Pharmaceuticals, Inc.

(Exact Name of Registrant Specified in Charter)

Delaware
(State or Other
Jurisdiction of
Incorporation)

000-50855
(Commission File
Number)

23-3016883
(I.R.S. Employer
Identification No.)

640 Lee Road
Chesterbrook, PA
(Address of Principal Executive Offices)

19087
(Zip Code)

Registrant's telephone number, including area code: **(484) 321-5900**

Not Applicable

(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
-
-

Item 7.01 Regulation FD Disclosure.

On January 28, 2013, Auxilium Pharmaceuticals, Inc. and Xstelos Holdings, Inc. (OTCQB: XTLS) announced that they filed a lawsuit against Upsher-Smith Laboratories, Inc. (“USL”) for infringement of ten U.S. patents covering Testim[®], 1% testosterone gel, that are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the U.S. Food and Drug Administration (“FDA”). These ten patents are owned by FCB I LLC, an indirect majority owned subsidiary of Xstelos, and are exclusively licensed to Auxilium. Xstelos holds the assets of CPEX Pharmaceuticals, Inc., the predecessor owner of the patents. The lawsuit was filed in the United States District Court for the District of Delaware on January 28, 2013.

The foregoing is qualified in its entirety by the text of the joint press release attached as Exhibit 99.1 hereto and incorporated herein by reference. All readers are encouraged to read the entire text of the joint press release attached hereto.

Item 8.01 Other Events.

On January 28, 2013, Auxilium Pharmaceuticals, Inc. and Xstelos Holdings, Inc. (OTCQB: XTLS) filed a lawsuit against Upsher-Smith Laboratories, Inc. (“USL”) for infringement of ten U.S. patents covering Testim[®], 1% testosterone gel, that are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the U.S. Food and Drug Administration (“FDA”). These ten patents are owned by FCB I LLC, an indirect majority owned subsidiary of Xstelos, and are exclusively licensed to Auxilium. Xstelos holds the assets of CPEX Pharmaceuticals, Inc., the predecessor owner of the patents. The lawsuit was filed in the United States District Court for the District of Delaware.

Auxilium and Xstelos filed this lawsuit in response to a notice letter sent by USL regarding its filing with the FDA of New Drug Application (“NDA”) No. 204399 for a 1% testosterone gel product. This letter also stated that NDA No. 204399 contained Paragraph IV certifications, under 21 U.S.C. Section 314.52(c) of the Federal Food, Drug, and Cosmetic Act, with respect to the ten patents listed in the Orange Book as covering Testim: U.S. Patent Nos. 7,320,968; 7,608,605; 7,608,606; 7,608,607; 7,608,608; 7,608,609; 7,608,610; 7,935,690; 8,063,029; and 8,178,518. These ten patents are expected to expire on various dates ranging from April 21, 2023 through January 18, 2025. Auxilium and Xstelos remain committed to protecting their intellectual property rights, including their patent protection for Testim.

Under the Hatch-Waxman Act, as a result of the patent infringement lawsuit filed against USL, final FDA approval of USL’s NDA for its proposed generic version of Testim will be stayed until at least the earlier of 30 months from the date USL’s notice letter was received (*i.e.*, June 24, 2015) or final resolution of the pending patent infringement lawsuit. While USL may receive tentative approval from the FDA for its version of Testim before one of those events occurs, it would not be permitted to launch its generic product in the U.S. until it receives the necessary final approval of its NDA from the FDA.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

99.1 Joint Press Release, dated January 28, 2013, issued by Auxilium Pharmaceuticals, Inc. and Xstelos Holdings, Inc.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this Report to be signed on its behalf by the undersigned hereunto duly authorized.

AUXILIUM PHARMACEUTICALS, INC.

Date: January 28, 2013

By: /s/ Andrew I. Koven

Andrew I. Koven

Chief Administrative Officer and General Counsel

4

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description of Exhibit</u>
99.1	Joint Press Release, dated January 28, 2013, issued by Auxilium Pharmaceuticals, Inc. and Xstelos Holdings, Inc.

5



**Auxilium Pharmaceuticals, Inc. and Xstelos Holdings, Inc. File Lawsuit
Against Upsher-Smith Laboratories, Inc. for Infringement of Testim® Patents**

MALVERN, PA and NEW YORK, NY, January 28, 2013 – Auxilium Pharmaceuticals, Inc. (NASDAQ: AUXL) (“Auxilium”) and Xstelos Holdings, Inc. (OTCQB: XTLS) (“Xstelos”) announced today that they filed a lawsuit against Upsher-Smith Laboratories, Inc. (“USL”) for infringement of ten U.S. patents covering Testim, 1% testosterone gel, that are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (commonly known as the Orange Book), published by the U.S. Food and Drug Administration (“FDA”). These ten patents are owned by FCB I LLC, an indirect majority owned subsidiary of Xstelos, and are exclusively licensed to Auxilium. Xstelos holds the assets of CPEX Pharmaceuticals, Inc., the predecessor owner of the patents. The lawsuit was filed in the United States District Court for the District of Delaware on January 28, 2013.

Auxilium and Xstelos filed this lawsuit in response to a notice letter sent by USL regarding its filing with the FDA of New Drug Application (“NDA”) No. 204399 for a 1% testosterone gel product. This letter also stated that NDA No. 204399 contained Paragraph IV certifications, under 21 U.S.C. Section 314.52(c) of the Federal Food, Drug, and Cosmetic Act, with respect to the ten patents listed in the Orange Book as covering Testim: U.S. Patent Nos. 7,320,968; 7,608,605; 7,608,606; 7,608,607; 7,608,608; 7,608,609; 7,608,610; 7,935,690; 8,063,029; and 8,178,518. These ten patents are expected to expire on various dates ranging from April 21, 2023 through January 18, 2025. Auxilium and Xstelos remain committed to protecting their intellectual property rights, including their patent protection for Testim.

Under the Hatch-Waxman Act, as a result of the patent infringement lawsuit filed against USL, final FDA approval of USL’s NDA for its proposed generic version of Testim will be stayed until at least the earlier of 30 months from the date USL’s notice letter was received (*i.e.*, June 24, 2015) or final resolution of the pending patent infringement lawsuit. While USL may receive tentative approval from the FDA for its version of Testim before one of those events occurs, it would not be permitted to launch its generic product in the U.S. until it receives the necessary final approval of its NDA from the FDA.

About Auxilium

Auxilium is a specialty biopharmaceutical company with a focus on developing and marketing products to predominantly specialist audiences. Auxilium markets Testim® 1% (testosterone gel) for the topical treatment of hypogonadism and XIAFLEX® (collagenase clostridium histolyticum) for the treatment of adult Dupuytren’s contracture patients with a palpable cord in the U.S. GlaxoSmithKline LLC co-promotes Testim with Auxilium in the U.S. Ferring International Center S.A. markets Testim in certain countries of the EU and Paladin Labs Inc. markets Testim in Canada. Pfizer Inc. has marketing rights for XIAPEX® (the EU tradename for collagenase clostridium histolyticum) in 46 countries in Eurasia through April 24, 2013; Asahi Kasei Pharma Corporation has development and commercial rights for XIAFLEX in Japan; and Actelion Pharmaceuticals Ltd has development and commercial rights for XIAFLEX in Canada, Australia, Brazil and Mexico. The sBLA for XIAFLEX for the treatment of Peyronie’s disease was submitted to the FDA on November 6, 2012 and has been accepted for standard review with a PDUFA date of September 6, 2013. Additionally, collagenase

clostridium histolyticum (“CCH”) is in phase IIa of development for the treatment of Frozen Shoulder syndrome (adhesive capsulitis) and phase Ib of development for the treatment of cellulite (edematous fibrosclerotic panniculopathy). Auxilium also has rights to pursue additional indications for CCH.

About Xstelos

Xstelos is a holding company formed for the purpose of holding the assets of CPEX Pharmaceuticals, Inc., an indirect, majority owned subsidiary of Xstelos. FCB I LLC is a wholly owned subsidiary of CPEX Pharmaceuticals, Inc.

Subject to certain exceptions, including prior exemption by Xstelos' board of directors, Xstelos' Certificate of Incorporation prohibits and makes void ab initio certain transfers of its common stock, to the extent that after giving effect to such purported transfer (i) the purported transferee would become a 4.75% or greater holder of its common stock, (ii) the ownership of a 4.75% stock holder' s common stock, prior to giving effect to the purported transfer, would be increased or (iii) the transfer creates a new "public group" under Treasury Section 1.382-2T(j)(3)(i).

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

This news release contains forward-looking statements as defined by the Private Securities Litigation Reform Act of 1995, including statements made with respect to Auxilium' s strategy, progress and timing of development programs and related trials, the efficacy of its product candidates, the commercial benefits available to it as a result of its agreements with third parties, future operations, financial position, future revenues, projected costs, prospects, plans and objectives of management and other statements regarding matters that are not historical facts, and involve predictions. These statements involve known and unknown risks, uncertainties and other factors that may cause actual results, performance, achievements or prospects to be materially different from any future results, performance, achievements or prospects expressed in or implied by such forward-looking statements. In some cases you can identify forward-looking statements by terminology such as ' may' , ' will' , ' should' , ' would' , ' expect' , ' intend' , ' plan' , ' anticipate' , ' believe' , ' estimate' , ' predict' , ' potential' , ' seem' , ' seek' , ' future' , ' continue' , or ' appear' or the negative of these terms or similar expressions, although not all forward-looking statements contain these identifying words. No specific assurances can be given with respect to whether: Auxilium will succeed in its efforts in defense of the patents covering Testim, including enforcement of its intellectual property rights and approved labeling, whether USL will be subject to a 30-month stay of its efforts to launch a generic competitor to Testim, the timing of any such launch by USL or the expected duration of any patent covering Testim. Although forward-looking statements are based on Auxilium' s current plans or assessments that are believed to be reasonable as of the date of this press release, they inherently involve certain risks and uncertainties. These forward-looking statements are subject to a number of risks and uncertainties, including those discussed under ' Risk Factors' ' in Auxilium' s Annual Report on Form 10-K for the year ended December 31, 2011, each of Auxilium' s Quarterly Reports on Form 10-Q for the three months ended September 30, 2012, June 30, 2012 and March 31, 2012 and Auxilium' s preliminary prospectus supplement and Current Report on Form 8-K, each filed with the Securities and Exchange Commission (the "SEC") on January 23, 2013. While Auxilium may elect to update the forward-looking statements made in this news release in the future, Auxilium specifically disclaims any obligation to do so. Auxilium' s SEC filings may be accessed electronically by means of the SEC' s home page on the Internet at <http://www.sec.gov>. There may be additional risks that Auxilium does not presently know or that Auxilium currently believes are immaterial which could also cause actual results to differ from those contained in the forward-looking statements.

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

This press release contains statements that are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements are based on current expectations, estimates and projections about Xstelos' business based, in part, on assumptions made by management. These statements are not guarantees of future performance and involve risks, uncertainties and assumptions that are difficult to predict. Therefore, actual outcomes and results may differ materially from what is expressed or forecasted in such forward-looking statements due to numerous factors, including those described above and the following: the expectation that Xstelos' business and operations will continue as presently conducted; competition from existing products or new products that may emerge; regulatory difficulties relating to products that have already received regulatory approval; potential product liability claims; Xstelos' dependency on third-party manufacturers to supply or manufacture Xstelos' products; Xstelos' ability to establish or maintain collaborations, licensing or other arrangements; Xstelos' ability and third parties' abilities to protect intellectual property rights; limitations of Xstelos' ability to utilize its net operating losses; compliance with obligations under intellectual property

licenses with third parties; Xstelos' ability to successfully invest for future growth; and other risks discussed from time to time in Xstelos' Securities and Exchange Commission filings and reports. In addition, such statements could be affected by general industry and market conditions and growth rates, and general domestic and international economic conditions. Such forward-looking statements speak only as of the date on which they are made, and Xstelos does not undertake any obligation to update any forward-looking statement to reflect events or circumstances after the date of this release.

Auxilium Contacts:

James E. Fickenscher/CFO
Auxilium Pharmaceuticals, Inc.
(484) 321-5900
jfickenscher@auxilium.com

William Q. Sargent Jr./ VP IR
Auxilium Pharmaceuticals, Inc.
(484) 321-5900
wsargent@auxilium.com

Xstelos Contact:

Xstelos Holdings, Inc.
Jonathan M. Couchman
President, Chief Executive Officer and Chief Financial Officer
(212) 729-4962
