FORM 8-K

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AUXILIUM PHARMACEUTICALS INC
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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 23, 2013**

Auxilium Pharmaceuticals, Inc.

(Exact Name of Registrant Specified in Charter)

Delaware	**000-50855**	**23-3016883**
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

640 Lee Road **Chesterbrook, PA**	**19087**
(Address of Principal Executive Offices)	(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 8.01 Other Events.

Auxilium Pharmaceuticals, Inc. previously disclosed certain risks related to its business and operations, that we believe should be considered in evaluating our business, financial position, future results and prospects. We disclosed these risks in Part I, Item 1A "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2011 (our "Form 10-K"), in "Item 1A − Risk Factors" of Part II of our Quarterly Report on Form 10-Q for the quarter ended March 31, 2012, in "Item 1A − Risk Factors" of Part II of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2012, and in "Item 1A − Risk Factors" of Part II of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012. The information presented below updates and supplements those risk factors for the matters identified below and should be read in conjunction with the risks and other information contained in our Form 10-K and Quarterly Reports. The risks described in our Form 10-K, as updated as described above and in this Report, are not the only risks we face. Additional risks that we do not presently know or that we currently believe are immaterial could also materially and adversely affect any of our business, financial position, future results or prospects. Additional risk factors that we believe should be considered are set forth below.

Our products and any of our product candidates, if approved, may face competition from lower cost generic or follow-on products and such generic competition could have a material adverse effect on our business.

Testim is approved under the provisions of the U.S. Food, Drug and Cosmetic Act that renders it susceptible to potential competition from generic manufacturers via the Abbreviated New Drug Application ("ANDA") procedure. Generic manufacturers can sell their products at prices much lower than those charged by the innovative pharmaceutical companies who have incurred substantial expenses associated with the research and development of the drug product.

The ANDA procedure includes provisions allowing generic manufacturers to challenge the effectiveness of the innovator' s patent protection long before the generic manufacturer actually commercializes their products through the paragraph IV certification procedure. In recent years, generic manufacturers have used paragraph IV certifications extensively to challenge patents on a wide array of innovative pharmaceuticals, and we expect this trend to continue and to implicate drug products with even relatively small total revenues.

ANDA Litigation with Upsher-Smith

We are currently engaged in separate litigations in Federal courts in Delaware and New Jersey with Upsher-Smith Laboratories, Inc. ("Upsher-Smith") regarding Upsher-Smith' s attempts to bring a generic testosterone gel product to market via an Abbreviated New Drug Application ("ANDA") using Testim as its reference drug. We refer to the litigation in Delaware as the "Delaware Upsher-Smith Litigation", the litigation in New Jersey as the "New Jersey Upsher-Smith Litigation", and both of them collectively as the "Upsher-Smith Litigations". A discussion of the Upsher-Smith Litigations is set forth below. For further discussion of the Upsher-Smith Litigations and Upsher-Smith' s efforts to obtain approval of a generic version of Testim via an ANDA pathway, see:

- "Competition−TRT Market Competition−Generic Competition" in Part I, Item 1 of our Annual Report on Form 10-K for the year ended December 31, 2011 (our "Form 10-K"); and
- "Legal Proceedings − Upsher-Smith Litigation" in Part II, Item 1 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.

Delaware

In October 2008, we and our licensor, CPEX Pharmaceuticals, Inc. (FCB I LLC' s ("FCB") predecessor in interest to Testim), received notice that Upsher-Smith filed an ANDA containing a paragraph IV certification seeking approval from the U.S Food and Drug Administration ("FDA") to market a generic version of Testim prior to the January 2025 expiration of the '968 Patent. Shortly after, we commenced the Delaware Upsher-Smith Litigation. Upsher-Smith will not be able to lawfully launch a generic version of Testim in the U.S. without the necessary approval from the FDA. Although it would seem unlikely based on the FDA' s public statements in its responses to the Citizen' s Petitions submitted by each of us and Abbott Laboratories ("Abbott") and Upsher-Smith' s public stance that its generic product has different penetration enhancers than Testim, the FDA could approve the generic product proposed in Upsher-Smith' s ANDA. With FDA approval, even if the Delaware Upsher-Smith Litigation remains pending, Upsher-Smith may nevertheless choose to launch this generic product, if approved, at risk of infringing the '968 patent. Although administratively closed in December 2011, the Delaware Upsher-Smith Litigation has not been dismissed or finally resolved and could also result in a finding that Upsher-Smith' s proposed testosterone product does not infringe the '968 Patent or that the '968 Patent is invalid and/or unenforceable. All discovery obligations of the parties continue to be in effect. In April 2012, we and FCB received a notice from Upsher-Smith in connection with its ANDA advising us and FCB of Upsher-Smith' s Paragraph IV certification relating to the eight additional patents listed in the Orange Book in addition to the '968 patent-in-suit, and asserting that Upsher-Smith does not believe that the product for which it is seeking approval infringes any of the Orange Book listed Testim patents and that those patents are invalid. A tenth U.S. patent issued to FCB on May 15, 2012 and was listed in the Orange Book.

New Jersey

We and FCB learned on September 11, 2012 that Upsher-Smith had filed on September 10, 2012 in the United States District Court for the District of New Jersey a complaint for declaratory judgment seeking a declaration of non-infringement and/or invalidity of FCB' s U.S. Patent Nos.: 7,608,605; 7,608,606; 7,608,607; 7,608,608; 7,608,609; 7,608,610; 7,935,690; and 8,063,029. All of the eight referenced patents cover our Testim® 1% testosterone gel, and the eight referenced patents are among the ten FCB patents covering Testim that are currently listed in the Orange Book. The referenced patents will expire between 2023 and 2025. We and FCB have filed a Motion to Dismiss this case.

505(b)(2) NDA and Paragraph IV Certification from Upsher Smith

On or about December 28, 2012, we and FCB became aware of a notice from Upsher-Smith that advised us and FCB of Upsher-Smith' s filing of a 505(b)(2) New Drug Application ("505(b)(2) NDA") containing a Paragraph IV certification under 21 U.S.C. Section 314.52(c) for testosterone gel (the "Upsher-Smith NDA"). This Paragraph IV certification notice refers to the ten U.S. patents, covering Testim® 1% testosterone gel, that are listed in the Orange Book. These ten patents are owned by FCB and will expire between 2023 and 2025. Upsher-Smith may seek to have any drug approved under the Upsher-Smith NDA as a generic version of Testim. For further discussion of this matter, see Item 8.01 of our Current Report on Form 8-K, filed on January 3, 2013.

ANDA Litigation with Watson

On May 24, 2012, we and FCB filed a lawsuit against Watson Laboratories, Inc. (NV); Watson Pharmaceuticals, Inc.; and Watson Pharma, Inc. (collectively, "Watson") for infringement of FCB' s ten patents listed in the Orange Book as covering Testim® 1% testosterone gel (the "Watson Litigation"). The lawsuit was filed in the United States District Court for the District of New Jersey on May 23, 2012

in response to a notice letter, dated April 12, 2012, sent by Watson Laboratories, Inc. (NV) regarding its filing with the FDA of an ANDA for a generic 1% testosterone gel product. This letter also stated that the ANDA contained Paragraph IV certifications with

respect to the nine patents listed in the Orange Book on that date as covering Testim. Our lawsuit filed against Watson involves those nine patents, as well as a tenth patent covering Testim that was issued on May 15, 2012 and is listed in the Orange Book. For further discussion of the Watson Litigation and Watson' s efforts to obtain approval of a generic version of Testim via an ANDA pathway, see "Legal Proceedings − Watson Litigation" in Part II, Item 1 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.

An adverse outcome in any of the Upsher-Smith Litigations, including any litigation that might result from the Upsher-Smith NDA, the Watson Litigation, or any other such legal action, could result in one or more generic versions of Testim being launched in the U.S. before the expiration of the last to expire of the ten Orange Book patents relating to Testim in January 2025. In addition, we expect that a generic version of Androgel may potentially be introduced as early as August 2015. See "Competition−TRT Market Competition−Generic Competition" in Part I, Item 1 of our Form 10-K for a discussion of Watson' s litigation involving Androgel. Since Testim and XIAFLEX for Dupuytren' s are currently our only products, the introduction of a generic version to Testim or Abbot' s AndroGel testosterone gel franchise could have a material adverse effect on our ability to successfully execute our business strategy to maximize the value of Testim as we continue the commercialization of XIAFLEX for Dupuytren' s.

In addition, the Patient Protection and Affordable Care Act and the associated reconciliation bill, enacted in March 2010, include provisions covering biological product exclusivity periods and a specific reimbursement methodology for biosimilars. As a new biological product, we expect that XIAFLEX will be eligible for 12 years of marketing exclusivity from the date of its approval by the FDA (although this could change as the regulations are enacted). The Patient Protection and Affordable Care Act also establishes an abbreviated licensure pathway for products that are biosimilar to or interchangeable with FDA-approved biological products, such as XIAFLEX. As a result, we could face competition from other pharmaceutical companies that develop biosimilar versions of our biological product XIAFLEX that do not infringe our patents or other proprietary rights. Similar legislation has also been adopted in the EU.

We have only limited patent protection for our products and our product candidates, and we may not be able to obtain, maintain and protect proprietary rights necessary for the development and commercialization of our products or our product candidates.

Our business and competitive positions are dependent upon our ability to obtain and protect our proprietary position for our products and our product candidates in the U.S., Canada, Europe and elsewhere throughout the world. We attempt to protect our intellectual property position by filing or obtaining licenses to patents and patent applications and, where appropriate, patents and patent applications in other countries related to our proprietary technology, inventions and improvements that are important to the development of our business.

Our and our licensors' patents and patent applications may not protect our technologies and products because, among other things:

- there is no guarantee that any of our or our licensors' pending patent applications will result in issued patents;
- we may develop additional proprietary technologies that are not patentable;
- there is no guarantee that any patents issued to us, our collaborators or our licensors will provide us with any competitive advantage or cover our product candidates;

- there is no guarantee that any patents issued to us or our collaborators or our licensors will not be challenged, interfered with, circumvented or invalidated by third parties; and

- there is no guarantee that any patents previously issued to others or issued in the future will not have an adverse effect on our ability to do business.

If we fail to obtain adequate patent protection for our products, our ability to compete could be impaired.

We may not control the patent prosecution, maintenance or enforcement of our in-licensed technology. Consequently, such licensed patents could be held invalid or unenforceable or could have claims construed in a manner adverse to our interests in litigation, which we would not control or to which we would not be a party. If any of the intellectual property rights of our licensors is found to be invalid, this could have a material adverse impact on our operations.

Testosterone, the active ingredient in Testim, is off-patent and is included in competing TRT products. In the U.S., the '968 Patent covers a method for maintaining blood serum testosterone levels for treating a hypogonadal male using Testim and is listed in the Orange Book. The '968 Patent expires in January 2025. Nine additional U.S. patents issued between 2009 and 2012 covering the composition of Testim and methods of its use and have been listed in the Orange Book. They expire in April 2023. Our licensor, FCB, also has filed continuation applications that are currently pending.

We are currently party to patent infringement litigations against each of Upsher-Smith and Watson relating to Upsher-Smith' s and Watson' s respective intentions to market a generic version of Testim prior to the expiration of the patents listed in the Orange Book covering Testim. Also, we have recently received a Paragraph IV certification from Upsher-Smith with respect to the Upsher-Smith NDA for a generic version of Testim, although no litigation has yet commenced. See "Competition−TRT Market Competition−Generic Competition" in Part I, Item 1 of our Form 10-K for discussion of the Upsher-Smith Litigation. See also "Legal Proceedings" in Part II, Item 1 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 for an update on the Upsher-Smith Litigations and a discussion of the Watson Litigation. See Item 8.01 of our Current Report on Form 8-K, filed on January 3, 2013, for a discussion of the Upsher-Smith NDA.

An adverse outcome in any of the Upsher-Smith Litigations, including any litigation that might result from the Upsher-Smith NDA, the Watson Litigation, or any other such legal action, could result in one or more generic versions of Testim being launched in the U.S. before the expiration of the last to expire of the ten Orange Book patents relating to Testim in January 2025. Since Testim and XIAFLEX for Dupuytren' s are currently our only products, the introduction of a generic version to Testim or Abbott' s AndroGel, which we believe may occur as early as August 2015, could have a material adverse effect on our ability to successfully execute our business strategy to maximize the value of Testim as we continue to seek to expand the market of the commercial launch of XIAFLEX for Dupuytren' s.

The standards that the USPTO and its foreign counterparts use to grant patents are not always applied predictably or uniformly and can change. Limitations on patent protection in some countries outside the U.S. and the differences in what constitutes patentable subject matter in these countries may limit the protection we seek outside of the U.S. In the U.S., issued patent claims may be broadened, narrowed, or even cancelled as a result of post-issuance procedures instituted by us or third parties, including reissue, re-examination, and the new supplemental examination procedure enacted as part of the Leahy-Smith America Invents Act. In addition, laws of foreign countries may not protect our intellectual

property to the same extent as would laws of the U.S. Also, some countries will not grant patents on patent applications that are filed after the public sale or disclosure of the material claimed in the patent application. Failure to obtain adequate patent protection for our proprietary product candidates and technology would impair our ability to be commercially competitive in these markets. Accordingly, we do not know the degree of future protection for our proprietary rights or the breadth of claims allowed in any patents issued to us or others.

We also rely on trade secrets, know-how and technology, which are not protected by patents, to maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we generally seek to enter into confidentiality agreements with our employees, consultants and collaborators upon the commencement of a relationship with us. However, we may not obtain these agreements in all circumstances. Nor can we guarantee that these agreements will provide meaningful protection, that these agreements will not be breached, or that we will have an adequate remedy for any such breach. In addition, adequate remedies may not exist in the event of unauthorized use or disclosure of this information. Others may have developed, or may develop in the future, substantially similar or superior know-how and technology. In addition, our research collaborators and scientific advisors may have contractual rights to publish our data and other proprietary information, subject to our prior review. Publications by our research collaborators and scientific advisors containing such information, either with our permission or in contravention of the terms of their agreements with us, may impair our ability to obtain patent protection or protect our proprietary information. The loss or exposure of our trade secrets, know-how and other proprietary information, as well as independent development of similar or superior know-how, could harm our operating results, financial condition and future growth prospects. Many of our employees and consultants were, and many of our consultants may currently be, parties to confidentiality agreements with other companies. Although our confidentiality agreements with these employees and consultants require that they do not bring to us, or use without proper authorization, any third party' s proprietary technology, if they violate their agreements, we could suffer claims or liabilities.

We may have to engage in costly litigation to enforce or protect our proprietary technology or to defend challenges to our proprietary technology by our competitors or collaborators, which may harm our business, results of operations, financial condition and cash flow.

The pharmaceutical field is characterized by a large number of patent filings involving complex legal and factual questions, and, therefore, we cannot predict with certainty whether our licensed patents will be enforceable. Competitors or collaborators may have filed applications for, or have been issued, patents and may obtain additional patents and proprietary rights related to products or processes that compete with or are similar to ours. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. Litigation may be necessary to protect our proprietary rights, and we cannot be certain that we will have the required resources to pursue litigation or otherwise to protect our proprietary rights.

Competitors or collaborators may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement lawsuits, which are expensive and time-consuming. In any such proceeding, a court may decide that a patent of ours or one that we have licensed is not valid or is unenforceable, may narrowly interpret our patent claims or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover its technology. In particular, if a competitor were to file a paragraph IV certification under the Hatch-Waxman Act in connection with that competitor' s submission to the FDA of an ANDA or a 505(b)(2) NDA for approval of a generic version of any of our products for which we believed we held a valid patent, then we could initiate a lawsuit against such competitor claiming patent infringement and defending the relevant patent' s validity and enforceability. Depending on the facts and circumstances, the FDA may stay the approval of the ANDA or 505(b)(2) NDA for a generic version of any of our

products for 30 months so long as we initiate litigation against the filer of the ANDA or 505(b)(2) NDA within 45 days of receiving the paragraph IV certification. If, prior to the expiration of the 30-month stay, a court found that one of our patents was invalid or not infringed, then, notwithstanding the 30-month stay, the FDA would be permitted to approve the competitor' s ANDA or 505(b)(2) NDA resulting in a competitive generic product. In the event that the FDA did not grant the 30-month stay, the FDA would be permitted to approve the competitor' s ANDA or 505(b)(2) NDA; however, we could engage in legal proceedings, such as seeking an injunction to attempt to preclude the generic competitor from entering the market during the pendency of the patent litigation, but we may not prevail in which event the competitor could enter the market, despite the ongoing patent litigation. For example, in October 2008, we and our licensor, CPEX (FCB' s predecessor in interest to Testim), received notice that Upsher-Smith filed an ANDA containing a paragraph IV certification seeking approval from the FDA to market a generic version of Testim prior to the January 2025 expiration of the '968

Patent, which certification Upsher-Smith has since purported to amend to include reference to eight of the additional nine patents listed in the Orange Book relating to Testim at the time of such purported amendment. Also, in April 2012, we and FCB received a notice from Watson that advised us of Watson' s filing of the Watson ANDA for testosterone gel. This Paragraph IV certification notice refers to FCB' s nine U.S. patents covering Testim that were listed in the Orange Book at the time of such certification. A tenth U.S. patent issued on May 15, 2012 and was listed in the Orange Book, and our lawsuit against Watson includes assertion of infringement of the ten patents listed in the Orange Book covering Testim. In addition, we and FCB learned on September 11, 2012 that Upsher-Smith had filed on September 10, 2012 in the United States District Court for the District of New Jersey a complaint for declaratory judgment seeking a declaration of non-infringement and/or invalidity of FCB' s U.S. Patent Nos.: 7,608,605; 7,608,606; 7,608,607; 7,608,608; 7,608,609; 7,608,610; 7,935,690; and 8,063,029. All of the eight referenced patents cover our Testim® 1% testosterone gel, and the eight referenced patents are among the ten FCB patents covering Testim that are currently listed in the Orange Book. The referenced patents will expire between 2023 and 2025. We and FCB have recently filed a Motion to Dismiss this case. In addition, on or about December 28, 2012, we and FCB became aware of a notice from Upsher-Smith that advised us and FCB of Upsher-Smith' s filing of a 505(b)(2) NDA containing a Paragraph IV certification for testosterone gel. This Paragraph IV certification notice refers to the ten U.S. patents, covering Testim® 1% testosterone gel, that are listed in the Orange Book. These ten patents are owned by FCB and will expire between 2023 and 2025. See "Competition−TRT Market Competition−Generic Competition" in Part I, Item 1 of our Form 10-K for discussion of the Upsher-Smith Litigation and Upsher-Smith' s efforts to obtain approval of a generic version of Testim. See also "Legal Proceedings" in Part II, Item 1 of our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012 for an update on the Upsher-Smith Litigations and a discussion of the Watson Litigation. See Item 8.01 of our Current Report on Form 8-K, filed on January 3, 2013, for a discussion of the Upsher-Smith NDA.

If we do not receive regulatory approval to market XIAFLEX for the treatment of Peyronie' s disease in a timely manner, or at all, we may not be able to expand our revenues for XIAFLEX and our business could be materially affected.

In December 2012, the FDA accepted for filing our sBLA for XIAFLEX for the potential treatment of Peyronie' s disease. The FDA has designated a PDUFA target action date of September 6, 2013. As the FDA is not bound by, and has in the past missed, its PDUFA goals, it is unknown whether the review of our sBLA will be completed within the FDA review goals or will be delayed.

The FDA has broad discretion in the drug approval process. Even if we believe that we have demonstrated positive results from our preclinical and clinical trials of XIAFLEX for the treatment of Peyronie' s disease, our results from these preclinical and clinical trials may not be sufficient, in the judgment of FDA, to support marketing approval, or regulatory interpretation of our data and procedures may be unfavorable. The FDA may determine after review of our data for XIAFLEX for the treatment of

Peyronie' s disease that our application is insufficient, and decline to allow approval of XIAFLEX for the treatment of Peyronie' s disease.

Obtaining approval of a sBLA is inherently uncertain. Even after completing clinical trials and other studies, XIAFLEX for the treatment of Peyronie' s disease may not receive regulatory approval for many reasons, including the following:

- we may not be able to demonstrate to the satisfaction of the FDA that XIAFLEX for the treatment of Peyronie' s disease is safe and effective;
- the FDA may disagree with the design or conduct of our clinical trials or other studies;
- the results of our clinical trials or other studies may not demonstrate that the clinical and other benefits of XIAFLEX for the treatment of Peyronie' s disease outweigh its safety risks;

- the FDA' s interpretation of the data from our clinical trials or other studies may be different than ours;

- the FDA may decide that the data collected from our clinical trials and other studies of XIAFLEX for the treatment of Peyronie' s disease is not sufficient to support the approval of our sBLA; and

- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical and other study data insufficient for approval.

If the FDA does not approve our application, it may require that we conduct additional clinical or pre-clinical studies and submit that data before it will reconsider our application. Depending on the extent of these or any other studies, approval of any application that we subsequently submit may be delayed by several years, or may require us to expend more resources than we have available. It is also possible that additional studies, if performed and completed, may not be successful or considered sufficient by the FDA for approval or even to make our application approvable. As a result, we cannot predict when or whether regulatory approval will be obtained for our sBLA for XIAFLEX for the treatment of Peyronie' s disease.

Even if XIAFLEX for the treatment of Peyronie' s disease receives regulatory approval from the FDA, any approvals that we obtain could contain significant limitations in the form of narrow indications, warnings, precautions or contra-indications with respect to conditions of use, or the requirement that we implement a risk evaluation and mitigation strategy. In such an event, our ability to generate revenues could be greatly reduced and our business could be harmed.

If we do not receive regulatory approval to market XIAFLEX for the treatment of Peyronie' s disease in a timely manner, or at all, we may not be able to expand our revenues for XIAFLEX and our business could be materially affected.

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 23, 2013

By: /s/ Andrew I. Koven
Andrew I. Koven
Chief Administrative Officer and General Counsel