KING PHARMACEUTICALS INC
Form 8-K
January 08, 2008

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 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 8, 2008 (January 2, 2008)
King Pharmaceuticals, Inc.

(Exact name of registrant as specified in charter)

Tennessee	001-15875	54-1684963
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

501 Fifth Street, Bristol, Tennessee	37620
(Address of principal executive offices)	(Zip Code)

Registrant s telephone number, including area code: (423) 989-8000

N/A

(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 (*see* General Instruction A.2. below):

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

Item 1.01. Entry into a Material Definitive Agreement.

On January 2, 2008, King Pharmaceuticals, Inc. (the Company) and King Pharmaceuticals Research and Development, Inc., a wholly-owned subsidiary of the Company (King R&D), entered into a Termination of Litigation Agreement (the Termination Agreement) with CorePharma, LLC (Core) relating to a patent infringement lawsuit previously filed by the Company and other third parties against Core. Additionally, on January 2, 2008, the Company and Core entered into a Metaxalone 800 mg Product Agreement (the Product Agreement) pursuant to which the Company granted to Core certain rights relating to an authorized generic version of the Company s 800 mg Skelaxin® product. Capitalized terms used but not defined herein shall have the meanings ascribed to them in the relevant agreement.

Termination of Litigation Agreement

On January 2, 2008, the Company entered into the Termination Agreement with Core in which the parties agreed to file a stipulation of dismissal with the United States District Court for the Eastern District of New York to dismiss all of the Company s claims and all of Core s counterclaims without prejudice. Additionally, the Company agreed to grant to Core a non-exclusive, personal, non-transferable and, subject to certain exceptions, non-assignable license to make, use, offer for sale, sell and import, in the United States, a 400 mg metaxalone product pursuant to Core s Abbreviated New Drug Application (ANDA) (expressly excluding any Section viii Product). The license is effective beginning on the earlier of (a) January 1, 2012 or (b) six months after the date of the first sale in the United States of a 400 mg generic version of Skelaxin® by a third party; provided, however, that such sale is not an unauthorized at risk launch triggered by either (i) a trial court determination that United States Patent Nos. 6,407,128 (the 128 patent) and 6,683,102 (the 102 patent), two method-of-use patents relating to Skelaxin®, are invalid, unenforceable or not infringed or (ii) the expiration of a 30 month stay precluding the United States Food and Drug Administration (the FDA) from granting to such third party final marketing approval for a generic version of Skelaxin®. In exchange for the grant of such license, Core agreed to withdraw the Section viii Statement filed in connection with its ANDA, to substitute a certification pursuant to 21 USC § 355(j)(2)(a)(vii)(III), and to refrain from filing additional Section viii Statements with the FDA relating to a metaxalone product. Subject to certain conditions, the parties further agreed to a mutual release of all claims relating to the lawsuit or any alleged infringement of the Company s patent rights by Core s 400 mg metaxalone product.

The Termination Agreement may only be terminated (a) upon mutual agreement of the Company and Core, (b) by either the Company or Core upon three months prior written notice if the other has materially breached the Termination Agreement or (c) by either the Company or Core if certain legal determinations are made or certain legal actions (as specified in the Termination Agreement) are taken that adversely affect the matters contemplated by the Termination Agreement or the 128 patent and the 102 patent.

The foregoing description of the Termination Agreement does not purport to be complete and is qualified in its entirety by reference to the Termination Agreement, which is attached hereto as Exhibit 10.1.

Product Agreement

On January 2, 2008, the Company and Core entered into the Product Agreement pursuant to which the Company granted to Core certain rights relating to an authorized generic version of the Company s 800 mg Skelaxin® product (Authorized Generic), as well as to Core s generic 800 mg metaxalone product pursuant to its ANDA (Core s 800 mg Product). With respect to Core s 800 mg Product, the Company granted to Core a non-exclusive, personal, non-transferable and, subject to certain exceptions, non-assignable license to make, use, offer for sale and import the product in the United States. This license becomes effective on the earlier to occur of (a) December 1, 2012, and (b) six

months after the date of the first sale in the United States of an 800 mg generic version of Skelaxin® by a third party; provided, however, that such sale is not an unauthorized at risk launch triggered by either (i) a trial court determination that the 128 patent and the 102 patent are invalid, unenforceable or not infringed or (ii) the expiration of a 30 month stay precluding the FDA from granting to such third party final marketing approval for a generic version of Skelaxin®. In exchange for the grant of such license, Core agreed to withdraw the Section viii Statement filed in connection with its ANDA for the Core 800 mg Product, to substitute a certification pursuant to 21 USC § 355(j)(2)(a)(vii)(III), and to refrain from filing additional Section viii Statements with the FDA relating to a generic metaxalone product. Subject to certain conditions, the parties further agreed to a mutual release of claims unrelated to Core s 800 mg Product.

With respect to the Authorized Generic, King granted Core the non-exclusive right to launch an Authorized Generic on the date that is the earliest of (a) December 1, 2012; (b) the date of the first sale in the United States of the first 800 mg generic version of Skelaxin® for which a Third Party has filed a certification with the FDA seeking approval to remove certain labeling information, pursuant to 21 USC § 355(j)(2)(a)(viii), or (c) six (6) months after the date of the first sale in the Territory of the first 800 mg generic version of Skelaxin® by a Third Party. King further authorized Core to launch an Authorized Generic immediately in the event a Third Party undertakes an at risk launch of an 800 mg generic metaxalone product, triggered by either (i) a trial court determination that the 128 patent and the 102 patent are invalid, unenforceable or not infringed or (ii) the expiration of a 30 month stay precluding the FDA from granting to such third party final marketing approval for a generic version of Skelaxin®. Core is obligated to discontinue its marketing and sale of the Authorized Generic, however, in certain circumstances if, in response to such an at risk launch , the Company prevails in precluding the continued marketing or sale of the third party generic version of Skelaxin®. Core is obligated to pay the Company a Distribution Fee on sales of Authorized Generic, which Core has the right to manufacture for its own sale pursuant to the Product Agreement.

The Product Agreement may be terminated by the Company in the event of certain product recalls relating to Skelaxin® or specified legal actions that preclude the continued sale of the Authorized Generic, and may be terminated with respect to the Authorized Generic alone if, due to certain legal obligations, the continued sale of the Authorized Generic adversely impacts King s Skelaxin® business. The Product Agreement may be terminated by either party for bankruptcy, uncured material breach or if a decision that all claims of the 102 patent and the 128 patent are invalid and/or unenforceable is entered by a court of competent jurisdiction from which decision no appeal (other than a petition for certiorari) has been or can be taken in an infringement case or declaratory judgment action.

The Company has terminated its previously disclosed exclusive arrangement with another generic pharmaceutical manufacturer related to the manufacture of an authorized generic metaxalone product.

The foregoing description of the Product Agreement does not purport to be complete and is qualified in its entirety by reference to the Product Agreement, which is attached hereto as Exhibit 10.2.

Background of Litigation

As previously described in the Company s filings with the Securities and Exchange Commission, Core, Eon Labs, Inc. (Eon Labs) and Mutual Pharmaceutical Co., Inc. (Mutual) each filed an ANDA with the FDA seeking permission to market a generic version of Skelaxin® 400 mg tablets. Additionally, Eon Labs ANDA seeks permission to market a generic version of Skelaxin® 800 mg tablets. The 128 patent and 102 patent are listed in the FDA s *Approved Drug Products with Therapeutic Equivalence Evaluations*, known as the Orange Book, and do not expire until December 3, 2021. Eon Labs and Core each filed Paragraph IV certifications against the 128 and 102 patents, alleging noninfringement,

invalidity and unenforceability of those patents. Mutual filed a Paragraph IV certification against the 102 patent alleging noninfringement and invalidity of that patent. A patent infringement suit was filed against Eon Labs on January 2, 2003 in the District Court for the Eastern District of New York; against Core on March 7, 2003 in the District Court for the District of New Jersey (subsequently transferred to the District Court for the Eastern District of New York); and against Mutual on March 12, 2004 in the District Court for the Eastern District of Pennsylvania concerning their proposed 400 mg products. Additionally, the Company filed a separate suit against Eon Labs on December 17, 2004 in the District Court for the Eastern District of New York, concerning its proposed 800 mg Skelaxin® product.

Pursuant to the Hatch-Waxman Act, the filing of the suit against Core triggered an automatic stay of FDA approval of Core s ANDA for 30 months (unless the patents are held invalid, unenforceable, or not infringed) from no earlier than January 24, 2003. Also pursuant to the Hatch-Waxman Act, the filing of the suits against Eon Labs provided the Company with an automatic stay of FDA approval of Eon Labs ANDA for its proposed 400 mg and 800 mg products for 30 months (unless the patents are held invalid, unenforceable, or not infringed) from no earlier than November 18, 2002 and November 3, 2004, respectively. The 30-month stay of FDA approval for Eon Labs ANDA for its proposed 400 mg product expired in May 2005. The 30-month stay of FDA approval for Eon Labs 800 mg product was tolled by the Court and has not expired yet. The Court has reserved judgment on the length of the tolling period. On May 17, 2006, the District Court for the Eastern District of Pennsylvania placed the Mutual case on the Civil Suspense Calendar pending the outcome of the FDA activity described below. On June 16, 2006, the District Court for the Eastern District of New York consolidated the Eon Labs cases with the Core case, and on April 30, 2007, Eon Labs 400 mg case was dismissed without prejudice. The Court also set a briefing schedule in the Core case for the Company s motion to dismiss for lack of case or controversy and for a Core motion for summary judgment of non-infringement. The motions were fully briefed by July 2007. The Court heard oral arguments on September 11, 2007 on these motions. On August 27, 2007, Eon also served a motion for summary judgment on the issue of non-infringement. The Court set a briefing schedule contingent on its decision in the Core case.

On March 9, 2004, the Company received a copy of a letter from the FDA to all ANDA applicants for Skelaxin® stating that the use listed in the FDA s Orange Book for the 128 patent may be deleted from the ANDA applicants product labeling. In response, the Company filed a Citizen Petition requesting the FDA to rescind that letter, require generic applicants to submit Paragraph IV certifications for the 128 patent, and prohibit the removal of information corresponding to the use listed in the Orange Book. The Company concurrently filed a petition for stay of action requesting the FDA to stay approval of any generic metaxalone products until the FDA has fully evaluated the Company s Citizen Petition.

On March 12, 2004, the FDA sent a letter to the Company explaining that the Company s proposed labeling revision for Skelaxin® was approvable and only required certain formatting changes. On April 5, 2004, the Company submitted amended labeling text that incorporated those changes. On April 5, 2004, Mutual filed a petition for stay of action requesting the FDA to stay approval of the Company s proposed labeling revision until the FDA has fully evaluated and ruled upon the Company s Citizen Petition, as well as all comments submitted in response to that petition. The Company, Core and Mutual have filed responses and supplements to their pending Citizen Petitions and responses. On December 8, 2005, Mutual filed another supplement with the FDA in which it withdrew its prior petition for stay, supplement, and opposition to the Company s Citizen Petition. On November 24, 2006, the FDA approved the revision to the Skelaxin® labeling. On February 13, 2007, the Company filed another supplement to the Company s Citizen Petition to reflect FDA approval of the revision to the Skelaxin® labeling. On May 2, 2007, Mutual filed comments in connection with the Company s supplemental submission. On July 27, 2007, Mutual filed another Citizen Petition in which it seeks a determination that Skelaxin® labeling should be revised to reflect the previously submitted data in its earlier submissions.

Other Relationships

Apart from the Termination Agreement and the Product Agreement, the Company and Core are also parties to a Skelaxin Manufacturing and Supply Agreement, dated as of May 11, 2006, pursuant to which Core manufactures and supplies Skelaxin® 800 mg tablets to the Company.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

10.1	Termination of Litigation Agreement, dated as of January 2, 2008, by and among the Company, King Pharmaceuticals Research & Development, Inc. and CorePharma LLC.
10.2	Metaxalone 800 mg Product Agreement, dated as of January 2, 2008, by and among the Company, King Pharmaceuticals Research & Development, Inc. and CorePharma LLC.

SIGNATURES

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.

Date: January 8, 2008

KING PHARMACEUTICALS, INC.

By: /s/ Brian A. Markison
Brian A. Markison
President and Chief Executive Officer

EXHIBIT INDEX

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