KING PHARMACEUTICALS INC
Form 8-K
February 28, 2006

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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): February 27, 2006

**King Pharmaceuticals, Inc.**

(Exact Name of Registrant as Specified in Its 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**

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))

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**Item 1.01. Entry into a Material Definitive Agreement.**

*The Dismissal Agreement*

On February 27, 2006, King Pharmaceuticals, Inc. ( King ) entered into a Dismissal Agreement (the Dismissal Agreement ) with Cobalt Pharmaceuticals, Inc., a Canadian company ( Cobalt ), and Aventis Pharma Deutschland GmbH, a German limited liability company ( Aventis ). The Dismissal Agreement pertains to the lawsuit filed by King and Aventis against Cobalt on March 14, 2003 (the Lawsuit ). The Lawsuit alleges that Cobalt infringed certain patent rights of Aventis and King related to ramipril, the active pharmaceutical ingredient in King s branded product Altace®, when Cobalt filed an Abbreviated New Drug Application ( ANDA ) with the U.S. Food and Drug Administration ( FDA ) on November 26, 2002, seeking approval to market a generic version of Altace® in the United States.

Under the Dismissal Agreement, within three days of the effective date of the agreement (which is determined as described below), the parties agreed to file a Stipulation of Dismissal with the United States District Court for the District of Massachusetts dismissing, without prejudice, all of King s and Aventis s claims against Cobalt in the Lawsuit. Cobalt agreed to provide King and Aventis with at least 30 days written notice prior to launching the generic version of Altace® under Cobalt s ANDA that was the subject of the Lawsuit; to provide King and Aventis with at least 30 days written notice prior to transferring or assigning its ANDA to any affiliate or third party or prior to granting any license, manufacturing, marketing or other right with respect to the ANDA to an affiliate or third party; and to bind any such affiliate or third party transferee to Cobalt s notice obligations to King and Aventis under the Dismissal Agreement.

Within five days after the execution and delivery of the Dismissal Agreement, Aventis will either (a) file a copy of the Dismissal Agreement with the U.S. Federal Trade Commission (the FTC ) and certain state attorneys general in connection with Aventis s consent decree with the FTC relating to diltiazem and notify King and Cobalt of the filing or (b) notify King and Cobalt that it has elected not to make the filing. In the event that Aventis makes such filing, the Dismissal Agreement will become effective on the 36th day following its execution. In the event that Aventis elects not to make the filing, the Dismissal Agreement will become effective on the sixth day following its execution.

Unless earlier terminated, the Dismissal Agreement will remain effective until the two patents asserted in the Lawsuit, which are related to Altace® and listed with the FDA, have expired. The Dismissal Agreement may be terminated (i) by mutual consent of all the parties; (ii) by any party, upon three months prior written notice to the other parties, if any other party is in material breach of the Dismissal Agreement and fails to timely cure the breach; or (iii) in certain circumstances, by any party, should an injunction or enforcement action be entered, enforced, pending or threatened making illegal or otherwise prohibiting the transactions contemplated by the Dismissal Agreement, or should any state or federal investigation relating to the Dismissal Agreement commence.

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*The First Amendment to the U.S. Product Agreement, and the Amended and Restated U.S. Product Manufacturing Agreement*

Also on February 27, 2006, King entered into a First Amendment to the U.S. Product Agreement (the Amendment ) with Sanofi-Aventis U.S. LLC (formerly, Hoechst Marion Roussel, Inc.), a Delaware company ( Sanofi-Aventis U.S. ), and Sanofi-Aventis Deutschland GmbH (formerly, Hoechst Marion Roussel Deutschland GmbH), a German company ( SAD and, together with Sanofi-Aventis U.S., Sanofi-Aventis ), as well as an Amended and Restated U.S. Product Manufacturing Agreement with SAD (the Restated Agreement ). The Amendment amends a U.S. Product Agreement that was originally entered into by the parties on December 17, 1998 and supplemented on June 30, 2000 (the Product Agreement ). The Restated Agreement supersedes the original U.S. Product Manufacturing Agreement entered into by the parties on December 17, 1998, and subsequently amended on June 22, 2000, December 16, 2002 and September 13, 2004 (the Original Manufacturing Agreement ). The Product Agreement and the Original Manufacturing Agreement relate collectively to the development, manufacture, use and sale by King in the United States and Puerto Rico (the U.S. Territory ) of drug products containing ramipril as an active pharmaceutical ingredient.

Under the Product Agreement, Sanofi-Aventis granted King certain rights to ramipril within the U.S. Territory, including certain patent and know-how rights. The Amendment provides that upon the expiration of the Exclusivity Term (which is the later to occur of October 29, 2008 and the date of expiration of any grant by the FDA to King of a pediatric exclusivity extension for King s product containing ramipril as the sole active ingredient, but no later than April 30, 2009), King s exclusive license to Combination Products (as defined below) under the Product Agreement becomes non-exclusive as to Sanofi-Aventis, but will continue as exclusive to any third parties; King s license to Mono Products (as defined below) remains exclusive for the remaining term of the Product Agreement; and King s licenses to make and have made drug products containing ramipril will no longer be tied to bulk ramipril supplied by Sanofi-Aventis. With respect to Combination Products, Sanofi-Aventis may not grant any out-license, except to third parties who are parties to a collaboration agreement with Sanofi-Aventis to jointly develop or jointly market Combination Products. In addition, the Amendment clarifies that King has the right to conduct clinical trials involving ramipril outside the U.S. Territory in order to obtain regulatory approvals for licensed product in the U.S. Territory, subject to applicable consent requirements under the Product Agreement, except in Canada for so long as Sanofi-Aventis continues to own patents or have exclusive in-licensed rights related to the ramipril compound, which patents have not been held invalid or unenforceable in a final, unappealable decision.

The Amendment further modifies the Product Agreement to provide that upon the expiration of the Exclusivity Term, the parties reciprocal access to product improvements containing ramipril and at least one additional active pharmaceutical ingredient ( Combination Products ) terminates. However, their reciprocal access to improvements to products containing ramipril as the sole active ingredient ( Mono Products ) continues, as does access to improvements developed prior to the end of the Exclusivity Term that have been offered to and accepted by the other party.

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In addition, the Amendment specifically provides that, in the event the parties enter into a license agreement relating to combination products containing both ramipril and hydrochlorothiazide ( HCT ) as active pharmaceutical ingredients, King s exclusive license will continue to be exclusive under the terms of such HCT license agreement, and King will continue to have access to improvements for ramipril/HCT combination products after the Exclusivity Term under the terms of the HCT license agreement.

The Amendment also provides that if Sanofi-Aventis exercises its rights to liquidated damages under the Restated Agreement (as described below) and terminates the Restated Agreement, King s licenses under the Product Agreement would automatically become non-exclusive as to Sanofi-Aventis, but will continue as exclusive to any third parties, and each party s right to product improvements under the Product Agreement would terminate automatically, though rights to improvements developed prior to the termination of the Restated Agreement would continue on a non-exclusive basis in the same way as King s other licenses.

The Original Manufacturing Agreement established initial terms and conditions pursuant to which SAD would exclusively supply all of King s requirements for ramipril. The Original Manufacturing Agreement sets forth, among other things, certain minimum quantities to be purchased by King. The Restated Agreement likewise sets forth an annual minimum amount, and quarterly minimum amount, of ramipril that King is required to purchase from SAD for the remainder of the term. The annual minimum amount in the Restated Agreement is reduced from the amounts set forth in the Original Manufacturing Agreement. The Restated Agreement further provides that if a third party, other than Cobalt under rights granted to Cobalt by King, launches a generic version of Altace® in the U.S. Territory, King and SAD will negotiate in good faith the annual minimum requirements, and corresponding quarterly minimum requirements, that King will be required to purchase; however, no changes will be made to the price applicable to all purchases. The Restated Agreement also sets forth a reduced price that will be applicable to all purchases made above the minimum amounts.

SAD will continue to be King s exclusive supplier of ramipril until the Restated Agreement expires on October 29, 2008, unless any pediatric exclusivity extension is granted to King by the FDA for King s product containing ramipril as the sole active ingredient, in which event the term of the Restated Agreement will continue for the term of such pediatric exclusivity extension but no later than April 30, 2009. The Restated Agreement also provides that, in the event that King fails to make its minimum quarterly payments, after a notice and cure period, SAD, at its sole discretion, may exercise its rights to liquidated damages, as well as terminate the Restated Agreement.

The foregoing descriptions of the Dismissal Agreement, the Amendment and the Restated Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of each such agreement, copies of which will be filed with King s Quarterly Report on Form 10-Q for the quarter ending March 31, 2006.

The press release announcing King s entry into the Dismissal Agreement is attached hereto as Exhibit 99.1, which is incorporated herein by reference.

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**Item 8.01**. **Other Events.**

On February 27, 2006, King issued a press release announcing its entry into the Dismissal Agreement, the full text of which is attached hereto as Exhibit 99.1.

**Item 9.01**. **Financial Statements and Exhibits**.

(d) The following exhibits are furnished with this report:

| Exhibit Number | Description |
|---|---|
| 99.1 | Press Release dated February 27, 2006 |

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**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.

King Pharmaceuticals, Inc.
(Registrant)

Date: February 28, 2006

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