KING PHARMACEUTICALS INC Form 8-K March 24, 2006

Table of Contents

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): March 24, 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

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 (*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))

TABLE OF CONTENTS

Item 8.01. Other Events.

Item 9.01. Financial Statements and Exhibits.

SIGNATURES

EX-99.1: PRESS RELEASE

Table of Contents

Item 8.01. Other Events.

On March 24, 2006, King Pharmaceuticals, Inc. (the Company) issued a press release announcing that, in recent communications with the U.S. Food and Drug Administration (FDA), the Company has been informed that the data from its completed TOPHAT (Treatment of Pediatric Hypertension with Altace Trial) clinical trial submitted in support of its supplemental New Drug Application (sNDA) are insufficient, and the Company believes that, subject to additional discussions with the FDA, it may be necessary to conduct a second clinical trial in order to receive an additional six months of exclusivity beyond patent expiry for the Company s Altace (ramipril) product. In light of this denial, the Company plans to have further discussions with the FDA and provide additional supportive analyses. If necessary, the Company also intends to pursue an additional clinical trial and meet with the FDA to reach agreement on the design of that trial. Should such an additional clinical trial be necessary, and provided that the study is completed and reported to the FDA by the third quarter of 2008 and that the results meet the FDA s requirements, the Company believes it can satisfy the applicable regulations and obtain an additional six months of market exclusivity. TOPHAT was initiated in response to the FDA s written request for additional information regarding Altacethat may produce health benefits in pediatric populations. This request was issued in accordance with the Modernization Act of 1997.

The press release, dated March 24, 2006, is being filed herewith as Exhibit 99.1 and the information contained therein is incorporated into Item 8.01 of this Current Report on Form 8-K by reference.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibit is filed with this report:

Exhibit Number Description

99.1 Press Release dated March 24, 2006

Table of Contents

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.

By: /s/ Joseph Squicciarino

Joseph Squicciarino Chief Financial Officer

Date: March 24, 2006