FORM 8-K

Current report filing

Filing Date: **2009-01-26** | Period of Report: **2009-01-23**
SEC Accession No. 0000950133-09-000126

FILER

KV PHARMACEUTICAL CO /DE/

CIK:**57055**| IRS No.: **430618919** | State of Incorp.:**DE** | Fiscal Year End: **0331**
Type: **8-K** | Act: **34** | File No.: **001-09601** | Film No.: **09544153**
SIC: **2834** Pharmaceutical preparations

Mailing Address
2503 S HANLEY RD
ST LOUIS MO 63144

Business Address
2503 S HANLEY RD
ST LOUIS MO 63144
3146456600

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 23, 2009

K-V Pharmaceutical Company

(Exact name of Registrant as specified in its charter)

Delaware	**1-9601**	**43-0618919**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)
2503 South Hanley Road **St. Louis, MO**		**63144**
(Address of principal executive offices)		(Zip Code)

Registrant' s telephone number, including area code: **(314) 645-6600**

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):

☐ 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.

Delayed Approval of Gestiva

As previously disclosed, K-V Pharmaceutical Company (the "Company") entered into a purchase agreement pursuant to which the Company will acquire the U.S. and worldwide rights to Gestiva™ (alpha hydroxyprogesterone caproate) upon approval of the pending New Drug Application (the "NDA") which was under review by the FDA. The Company previously announced that the PDUFA date for the NDA (which is the date by which the FDA is scheduled to issue a decision on whether to approve the application) was expected to be January 25, 2009. The Company has been informed by the current NDA applicant that the FDA will not approve Gestiva until additional data and information is submitted and accepted. The NDA applicant and the Company have agreed to certain FDA-suggested revisions to the protocol for a post-approval clinical trial that the parties had previously agreed to conduct. However, the agency has now concluded that an additional condition for approval, among others, will be that a portion of the study subjects must be enrolled in the study prior to final approval. As a result, the Company does not anticipate that it will generate revenues from sales of Gestiva during this fiscal year, which ends on March 31, 2009.

A copy of the Company' s press release, dated January 26, 2009, related to the matters discussed under this Item 8.01 is filed herewith as Exhibit 99.1.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated January 26, 2009*

* **Filed herewith**

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.

K-V Pharmaceutical Company

By: /s/ Ronald J. Kanterman
Ronald J. Kanterman
Vice President, Chief Financial Officer and Treasurer

Date: January 26, 2009

EXHIBIT INDEX

Exhibit No.	Description
99.1	Press Release, dated January 26, 2009*

* **Filed herewith**

Exhibit 99.1

KV Pharmaceutical
2503 South Hanley Road
St Louis, MO 63144

FOR IMMEDIATE RELEASE

KV Pharmaceutical' s Launch of Gestiva™ Delayed

ST. LOUIS – Jan. 26, 2009 - KV Pharmaceutical (NYSE: KVa/KVb) has been notified that the pending New Drug Application (NDA) for Gestiva™ (alpha hydroxyprogesterone caproate) will not be approved by the U.S. Food and Drug Administration (FDA) until further conditions are met.

As previously disclosed, KV Pharmaceutical entered into a purchase agreement to acquire the U.S. and worldwide rights to Gestiva upon approval of the pending NDA, which was under review by the FDA. The Company previously announced that the date on which the FDA was expected to issue a decision was January 25, 2009.

The Company has been informed by the current NDA applicant that the FDA will not approve Gestiva until additional data and information is submitted and accepted. The NDA applicant and the Company have agreed to certain FDA-suggested revisions to the protocol for a post-approval clinical trial that the parties had previously agreed to conduct. However, the agency has now concluded that an additional condition for approval, among others, will be that a portion of the study subjects must be enrolled in the study prior to final approval. As a result, the Company does not anticipate that it will generate revenues from sales of Gestiva during this fiscal year, which ends on March 31, 2009.

About KV Pharmaceutical Company

KV Pharmaceutical Company is a fully integrated specialty pharmaceutical company that develops, manufactures, markets, and acquires technology-distinguished branded and generic/non-branded prescription pharmaceutical products. The company markets its technology distinguished products through ETHEX Corporation, a national leader in generic pharmaceuticals and Ther-Rx Corporation, its branded drug subsidiary.

Contact:

Catherine Biffignani
KV Pharmaceutical Company
P: (314) 645-6600
E: cbiffignani@kvpharmaceutical.com