

# SECURITIES AND EXCHANGE COMMISSION

## FORM 8-K

Current report filing

Filing Date: **2009-01-26** | Period of Report: **2009-01-22**  
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### FILER

#### **KV PHARMACEUTICAL CO /DE/**

CIK: **57055** | IRS No.: **430618919** | State of Incorporation: **DE** | Fiscal Year End: **0331**  
Type: **8-K** | Act: **34** | File No.: **001-09601** | Film No.: **09544152**  
SIC: **2834** Pharmaceutical preparations

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3146456600

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**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

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**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 22, 2009**

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**K-V Pharmaceutical Company**

(Exact name of Registrant as specified in its charter)

**Delaware**  
(State or other jurisdiction of incorporation)

**1-9601**  
(Commission File Number)

**43-0618919**  
(IRS Employer Identification No.)

**2503 South Hanley Road  
St. Louis, MO**  
(Address of principal executive offices)

**63144**  
(Zip Code)

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

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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))
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## **Item 2.04. Triggering Events That Accelerate or Increase a Direct Financial Obligation or an Obligation under an Off-Balance Sheet Arrangement.**

(a) As described below under Item 8.01, K-V Pharmaceutical Company (the “Company”) announced certain actions with respect to the manufacturing and shipment of its products. As previously disclosed, the Company is a party to a credit agreement with ten lenders that provides for a revolving line of credit of up to \$320 million and has a five-year term expiring in June 2011. The credit agreement contains financial covenants that impose limits, requirements or restrictions on, among other things, minimum equity levels, a maximum senior leverage ratio and a minimum fixed charge coverage ratio. As of the date hereof, the Company had borrowings under the revolving line of credit of approximately \$30 million.

As a result of the events described under Item 8.01, the Company believes it is reasonably likely that, as of December 31, 2008, the Company may not have been in compliance with one or more of the covenants included in the credit agreement. However, the Company has not yet determined the financial results for the fiscal quarter ended December 31, 2008 necessary to complete the requisite calculations.

Unless a waiver is provided by the lenders in accordance with the terms of the credit agreement, failure by the Company to comply with one or more of the covenants constitutes an event of default pursuant to the credit agreement. As a result of any such default, the Company’s outstanding obligations under the credit agreement would accelerate and immediately become due and payable. The Company intends to engage in discussions with its lenders regarding a potential waiver of any breach, potential renegotiation of the terms of the credit agreement or other arrangements. The Company expects to provide additional disclosure regarding these matters in subsequent filings with the U.S. Securities and Exchange Commission (the “SEC”).

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

### FDA Activities

As the Company previously disclosed, the U.S. Food and Drug Administration (the “FDA”) began an inspection of the Company in December 2008. These inspectional activities continue and, in addition, representatives of the FDA’s Office of Criminal Investigations (“OCI”) have begun participating in discussions with the Company. The Company is fully cooperating with the FDA and, although the inspections are not yet complete, the Company has voluntarily taken a number of significant steps, as described below. Notwithstanding these voluntary actions, the FDA may take enforcement action against the Company, which could include administrative action, civil enforcement by means of judicial proceedings and criminal prosecution of the Company or individuals.

### Suspension of Manufacturing and Shipment; Product Recall

In connection with the FDA’s inspectional activities, effective January 22, 2009, the Company voluntarily suspended the manufacturing and shipment of all of its products, other than products it distributes but does not manufacture. Accordingly, the Company will continue to ship its Evamist™ (estradiol transdermal spray) product, its ketorolac tromethamine tablets and its enteric coated naproxen sodium tablets. The Company notes, however, that these three products do not generate a material amount of revenue for the Company.

Additionally, the Company is initiating a nationwide recall affecting most of the Company’s products. The scope and depth of the recall, which the Company is voluntarily implementing, are currently the subject of discussions with the FDA. The Company expects to provide additional disclosure regarding the product recall in subsequent filings with the SEC.

While the Company has not yet fully determined the impact of these actions on its financial condition, the Company expects these actions to have a material adverse effect on, among other things, the Company’s revenues, liquidity, assets and capital resources. The Company expects to incur significant costs resulting from, among other causes, the product recall, write-off of inventory and activities related to reentering the marketplace. The Company expects to provide additional disclosure regarding any financial impact in subsequent SEC filings.

The Company is discussing with the FDA a process for returning its products to market. The Company expects to provide additional disclosure regarding returning its products to market in subsequent SEC filings.

#### Formation of Special Committee of the Board of Directors

The Company's Board of Directors (the "Board") has appointed a Special Committee of the Board (the "Special Committee") consisting of the following members of the Board: Jean M. Bellin, Kevin S. Carlie, Terry B. Hatfield, Jonathon E. Killmer and Norman D. Schellenger. Mr. Hatfield, the Chairman of the Board, has been appointed to serve as the Chairman of the Special Committee. The Special Committee was formed in response to the initiation of a series of putative class action shareholder lawsuits alleging violations of the federal securities laws by the Company and certain individuals as well as the receipt by the Company of an informal inquiry from the SEC. The Company, at the direction of the Special Committee, is fully cooperating in all governmental matters, including the SEC informal inquiry. The Company is also responding to requests for information from the Office of the United States Attorney for the Eastern District of Missouri and FDA representatives working with that office. The Special Committee was delegated by the Board the authority to act on behalf of the Board with respect to these and all related government inquiries and litigation matters. The Special Committee has retained independent legal counsel.

A copy of the Company's press release, dated January 26, 2009, related to the matters discussed in this Form 8-K is filed herewith as Exhibit 99.1.

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

(d) Exhibits

**Exhibit No. Description**

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99.1 Press Release, dated January 26, 2009\*

\* Filed herewith

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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.

K-V Pharmaceutical Company

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

Date: January 26, 2009

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## EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release, dated January 26, 2009*

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\* **Filed herewith**



KV Pharmaceutical  
2503 South Hanley Road  
St Louis, MO 63144

FOR IMMEDIATE RELEASE

**KV Pharmaceutical Suspends Product Manufacturing, Shipping  
Announces Voluntary Product Recall  
Board of Directors Appoints Special Committee**

**ST. LOUIS – Jan. 26, 2009** - KV Pharmaceutical (NYSE: KVa/KVb) has voluntarily suspended the manufacturing and shipping of all of its products, other than certain products that it distributes but does not manufacture. The suspension began on January 22, 2009.

Additionally, the company will conduct a voluntary recall of most of its products. The scope and depth of the recall are currently under discussion with the U.S. Food and Drug Administration (FDA).

These actions are being taken in cooperation with the previously announced inspection by the FDA of the company's operations and inventory, which began in December. To resume shipments as quickly as possible, the company is working with a third-party consulting group, Lachman Consultant Services, Inc., to review manufacturing and packaging processes.

"The new leadership team at KV realizes that we are in a very challenging time for the company," said interim President and CEO David Van Vliet. "We are committed, however, to resolving these issues and resuming production as soon as possible by working closely with the FDA and the independent experts from Lachman Consultant Services."

KV expects these actions to have a material adverse effect on its financial condition, and as a result, may not be in compliance with one or more covenants included in a credit agreement with its lenders. As of December 31, 2008, the outstanding balance under this line of credit was approximately \$30 million.

The company's Board of Directors has appointed a special committee consisting of the following members of the Board: Jean M. Bellin, Kevin S. Carlie, Terry B. Hatfield, Jonathon E. Killmer and Norman D. Schellenger. Mr. Hatfield, the Chairman of the Board, has been appointed to serve as the Chairman of the special committee. The special committee was formed in response to the initiation of a series of putative class action shareholder lawsuits alleging violations of the federal securities laws by the company and certain individuals as well as the



receipt of an informal inquiry from the SEC. The company, at the direction of the special committee, is fully cooperating in all governmental matters, including the SEC informal inquiry. The company is also responding to requests for information from the Office of the United States Attorney for the Eastern District of Missouri and FDA representatives working with that office. The special committee was delegated by the Board the authority to act on behalf of the Board with respect to these and all related government inquiries and litigation matters. The special committee has retained independent legal counsel.

A detailed description of these events is contained in a Form 8-K that is being filed today with the SEC. The text of that document is available at the SEC's EDGAR website at [www.sec.gov](http://www.sec.gov).

### **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.

### **Safe Harbor**

*The information in this release may contain various forward-looking statements within the meaning of the United States Private Securities Litigation Reform Act of 1995 ("PSLRA") and which may be based on or include assumptions concerning KV's operations, future results and prospects. Such statements may be identified by the use of words like "plans", "expect", "aim", "believe", "projects", "anticipates", "commit", "intend", "estimate", "will", "should", "could" and other expressions that indicate future events and trends.*

*All statements that address expectations or projections about the future, including without limitation, product development, product launches, regulatory approvals, market position, acquisitions, revenues, expenditures, resumption of distribution of tablet-form products and the impact of the recall and suspension of shipments on revenues, and other financial results, are forward-looking statements.*

*All forward-looking statements are based on current expectations and are subject to risk and uncertainties. In connection with the "safe harbor" provisions, KV provides the following cautionary statements identifying important economic, political and technology factors, which among others, could cause actual results or events to differ materially from those set forth or implied by the forward-looking statements and related assumptions.*

*Such factors include (but are not limited to) the following: (1) changes in the current and future business environment, including interest rates and capital and consumer spending; (2) the difficulty of predicting FDA approvals, including timing, and that any period of exclusivity may not be realized; (3) acceptance and demand for new pharmaceutical products; (4) the introduction and impact of competitive products and pricing, including as a result of so-called authorized-generic drugs; (5) new product development and launch, including the possibility that any product launch may be delayed or that product acceptance may be less than anticipated; (6) reliance on key strategic alliances; (7) the availability of raw materials and/or products manufactured for the Company under contract manufacturing arrangements with third parties; (8) the regulatory environment, including regulatory agency and judicial actions and changes in applicable law or regulations; (9) fluctuations in revenues; (10) the difficulty of predicting*

*international regulatory approval, including timing; (11) the difficulty of predicting the pattern of inventory movements by the Company's customers; (12) the impact of competitive response to the Company's sales, marketing and strategic efforts, including the introduction or potential introduction of generic or competing products against products sold by the Company and its subsidiaries; (13) risks that the Company may not ultimately prevail in litigation, including challenges to our intellectual property rights by actual or potential competitors or to our ability to market generic products due to brand company patents and challenges to other companies' introduction or potential introduction of generic or competing products by third parties against products sold by the Company or its subsidiaries including without limitation the litigation and claims referred to in Note 16 of the Notes to the Consolidated Financial Statements in the Company's Form 10-Q for the quarter ended June 30, 2008; (14) the possibility that KV's current estimates of the financial effect of certain announced product recalls could prove to be incorrect; (15) whether any product recalls or product introductions result in litigation, agency action or material damages; (16) the possibility that the findings of the Audit Committee inquiry referenced in the Company's Form 10-Q for the quarter ended June 30, 2008, and Form 12b-25 filed with the SEC on November 13, 2008, could have a material impact on the Company's financial results; (17) the satisfaction or waiver of the other closing conditions in the previously disclosed Gestiva™ acquisition agreement; (18) the possibility that the auction rate securities held by the Company may not return to liquidity or at their face value; (19) the Company's voluntary suspension of the production and shipment of substantially all of the products that the Company manufactures and the related nationwide recall affecting substantially all of the products that the Company manufactures as well as the expected material adverse effect on the Company's revenue, assets and liquidity and capital resources, all as more fully described in this press release and in the Company's Form 8-K filed with the SEC on January 26, 2009; (20) the series of putative class action lawsuits alleging violations of the federal securities laws by the Company and certain individuals, all as more fully described in this press release and in the Company's Form 8-K filed with the SEC on January 26, 2009; (21) the informal inquiry initiated by the SEC and any related or additional governmental investigative or enforcement proceedings, including actions by the FDA and the U.S. Department of Justice, all as more fully described in this press release and in the Company's Form 8-K filed with the SEC on January 26, 2009; and (22) the risks detailed from time-to-time in the Company's filings with the SEC. This discussion is by no means exhaustive, but is designed to highlight important factors that may impact the Company's outlook. We are under no obligation to update any of the forward-looking statements after the date of this release.*

Contact:

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