


UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF MISSOURI  
EASTERN DIVISION

 Individually and on Behalf of )	No. 08-1859
All Others Similarly Situated, )	
Plaintiff, )	<u>CLASS ACTION</u>
vs. )	COMPLAINT FOR VIOLATION OF THE
KV PHARMACEUTICAL COMPANY, )	FEDERAL SECURITIES LAWS
MARC S. HERMELIN and RONALD J. )	<u>DEMAND FOR JURY TRIAL</u>
KANTERMAN, )	
Defendants. )	
_____ )	

## INTRODUCTION AND OVERVIEW

1. This is a class action for violations of the federal securities laws on behalf of all purchasers of KV Pharmaceutical Company (“KV” or the “Company”) publicly traded securities<sup>1</sup> between February 15, 2008 and November 12, 2008 (the “Class Period”), who were damaged thereby.

2. Defendant KV is a pharmaceutical company. During the Class Period, defendants made materially false and misleading statements about KV’s compliance with federal regulations concerning the manufacture and marketing of certain generic drug products as well as the Company’s current and future financial prospects. On November 11, 2008, the Company announced that it would be unable to file its Form 10-Q for the second fiscal quarter ended September 30, 2008 (“2Q09”)<sup>2</sup>, because of the continuing investigation by its audit committee (the “Audit Committee Investigation”) into allegations of “management misconduct” concerning KV’s regulatory and other compliance matters.

3. On November 13, 2008, the Company filed Form 12b-25 with the SEC confirming its inability to file its September 30, 2008 Form 10-Q and further announcing for the first time that the *Audit Committee Investigation was centered on management misconduct concerning certain generic drug product recalls*. In addition, defendants released a plethora of previously undisclosed setbacks related to certain product price erosion, discontinued products and manufacturing delays

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<sup>1</sup> At March 31, 2008, KV had three classes of registered securities issued and outstanding: *Class A Common Stock* – 40,764,603 shares issued and outstanding traded under the symbol KV-A on the NYSE. Class A common shares entitle the holder to one-twentieth of one vote on all matters; *Class B Common Stock* – 12,170,172 shares issued and outstanding traded under the symbol KV-B. Class B common shares entitle the holder to one vote on all matters; *7% cumulative convertible Preferred Stock* – 40,000 shares issued and outstanding. One share of KV’s Preferred Stock is convertible in to 8.375 shares of Class A Common Stock.

<sup>2</sup> KV’s 2009 fiscal year began on April 1, 2008.

and disruptions, leading to unexpected losses in 2Q09 and to defendants' "withdrawal of KV's revenue and earnings guidance for fiscal 2009, issued by Defendants just three months before.

4. Following these November 13th statements the price of KV common stock fell nearly 59% from \$14.26 per share to \$5.90 per share on extremely heavy volume of more than 6.6 million shares, thirty-three times the average trading volume for the stock.

#### **JURISDICTION AND VENUE**

5. The claims asserted arise under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("1934 Act"), 15 U.S.C. §§78j(b) and 78t(a), and Rule 10b-5, 17 C.F.R. §240.10b-5, promulgated thereunder. Jurisdiction is conferred by §27 of the 1934 Act, 15 U.S.C. §78aa.

6. Venue is proper here pursuant to Section 27 of the 1934 Act. KV maintains its principal executive offices in this district.

#### **THE PARTIES**

7. Plaintiff ██████████ purchased KV securities during the Class Period as set forth in the attached certification which is incorporated herein by reference and was damaged thereby.

8. Defendant KV is a pharmaceutical company with offices at 2503 South Hanley Road, St. Louis, Missouri.

9. Defendant Marc S. Hermelin ("Hermelin") was KV's Chairman and Chief Executive Officer ("CEO") at all relevant times.

10. Defendant Ronald J. Kanterman ("Kanterman") was KV's Vice President and Chief Financial Officer ("CFO") at all relevant times.

11. Defendant Richard H. Chibnall ("Chibnall") was KV's Vice President of Finance and Chief Accounting Officer.

12. The defendants identified in ¶¶9-11 are referred to herein as Individual Defendants.

## **BACKGROUND**

13. KV is a pharmaceutical company that develops, manufactures and markets generic and branded prescription drug products. The Company markets its generic products through ETHEX Corporation (“ETHEX”) and markets its branded products through Ther-Rx Corporation (“Ther-Rx”). Both ETHEX and Ther-Rx are wholly-owned subsidiaries of KV. During fiscal 2008, sales of KV’s generic drugs through ETHEX accounted for more than 60% of the Company’s total revenues.

14. During the Class Period defendants employed a host of artifices and schemes intended to artificially inflate the price of KV securities. KV issued numerous press releases announcing, among other things, its financial results and KV filed quarterly and annual reports with the SEC on Forms 10-Q and 10-K. The Company’s press releases and quarterly and annual reports filed with the SEC were each materially false and misleading because KV was misrepresenting its manufacturing practices and compliance with FDA regulations and enforcement notices. Moreover, defendants materially overstated KV’s reported results by failing to report losses stemming from product recalls and product discontinuations.

## **CLASS PERIOD EVENTS AND STATEMENTS**

15. On or about February 15, 2008, KV issued a press release announcing its financial results for the fiscal year ended March 31, 2007. KV’s reported fiscal 2007 results were unaudited and their release had been delayed due to the investigation by a Special Committee of independent members of the Board of Directors into the Company’s stock option grant practices.<sup>3</sup> Under the

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<sup>3</sup> The Special Committee investigation of the Company’s stock option grant practices resulted in the multi-year restatement of KV’s financial statements for the period 1996 through 2006. Pending the completion of the restatement, KV discontinued regular Form 10-Q and Form 10-K filings in November 2006. KV resumed filings in March 2008. KV filed delayed 10Q and 10K filings in March, 2008, for fiscal periods ended March 31, 2007, December 31, 2006 and September

banner headline, ***“KV Pharmaceutical Company Completes Unaudited Fiscal 2007 Results; Receives Trading Extension From NYSE; Fiscal 2007 Marked Record Profitability and 12th Consecutive Year of Record Revenues; KV Also Reports Preliminary Fiscal 2008 Third Quarter Revenues of \$164 Million, Up 39% from Prior Year,”*** the press release commented on the fiscal 2007 performance of KV’s generic drug business stating in pertinent part as follows:

KV’s specialty generic/non-branded subsidiary ETHEX Corporation, reported fiscal 2007 net revenues of \$235.6 million, an increase of \$31.8 million, or 15.6% compared to fiscal 2006 net revenues of \$203.8 million. Results for fiscal 2007 were attributable to continued growth in ETHEX’s existing product lines, with particular contribution from the cardiovascular, pain management and cough/cold lines . . . .

\* \* \*

ETHEX’s operating performance remained strong as measured by gross profit margins. Fiscal 2007 gross margin was 58.7%, up from 54.9% in fiscal 2006. ***The Company believes its gross margins remain significantly higher than average gross margins in the generic drug industry segment and that trend has continued with the subsequent approval and launch after fiscal 2007 year-end of metoprolol succinate extended release tablets (generic alternative to Toprol-XL®, AstraZeneca), 100 mg and 200 mg strengths for which the Company was granted a first-to-file approval and a six-months exclusivity period in the marketplace.***

The approval of metoprolol succinate extended release tablets was received during the first quarter of fiscal 2008. The 100 mg and 200 mg strengths of metoprolol succinate extended release tablets were launched during the second quarter of the Company’s current fiscal year, contributing \$50.4 million in net revenues to ETHEX Corporation during the second quarter launch period.

[Emphasis added.]

16. On or about February 25, 2008, KV issued a press release announcing its financial results for the quarter and nine months ended December 31, 2007 (“3Q08”). The Company reported net revenues for 3Q08 increased 38.8% to \$163.7 million, compared to \$117.9 million for the third

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30, 2006 and amended the 10Q filing for the June 30, 2006 quarter. In June, KV filed delayed 10Q and 10K filings for fiscal periods ended March 31, 2006, December 31, 2007, September 30, 2007 and June 30, 2007.

quarter of fiscal 2007. Ther-Rx net revenue grew 16.6% to \$56.3 million, while ETHEX net revenues rose 57.8% to \$102.2 million. The press release stated that ETHEX net revenue growth was positively affected by the 100 mg and 200 mg strengths of Metoprolol Succinate Extended Release Tablets (generic alternative to Toprol® XL, Astra Zeneca). Defendant Hermelin commented on the seeming positive results stating in pertinent part as follows:

KV enjoyed a solid third quarter, including growth at ETHEX due to continued revenue contribution from the 100 mg and 200 mg strengths of Metoprolol Succinate Extended Release Tablets and our Diltiazem HCl Extended-Release Capsules. With continuing momentum in our branded business, as well as the anticipated launch of Evamist™ during the fourth quarter, we expect to capitalize on our performance momentum during the remainder of fiscal 2008 and beyond.

17. On or about June 16, 2008, KV issued a press release announcing its financial results for the fourth quarter and year ended March 31, 2008 (“4Q08 PR”). The Company reported net revenues for the three months ended March 31, 2008 increased 27.0% to \$153.0 million compared to \$120.5 million for the fourth quarter of fiscal 2007 and net income for the quarter was \$9.3 million or \$0.18 per diluted Class A share. Defendant Hermelin commented on the Company’s seemingly positive results, stating in pertinent part as follows:

KV had a strong fiscal 2008 with each of the Company’s principal business units reporting record revenues and improved gross margins. We continued to exhibit a robust generic and branded pipeline during fiscal 2008, evidenced by our 16 ANDA’s filed, five generic product approvals from the FDA, the launch of Evamist™ and progress towards the pending approval for Gestiva™. Our branded business, Ther-Rx, continued to benefit from our leading women’s health products. ETHEX’s outstanding full year revenue growth of 56.1% was achieved through the approval, launch and contribution of two first-to-file strengths of Metoprolol Succinate Extended-Release Tablets.

***Overall, we believe KV is well positioned in both businesses for future growth and profitability. We remain positive about the Company’s overall prospects from existing products as well as anticipated new product introductions.***

[Emphasis added.]

18. The 4Q08 PR also highlighted the historical performance and 2009 growth prospects for ETHEX’s generic cardiovascular drug Metoprolol Succinate, stating in pertinent part as follows:

*Revenues*

- KV's specialty generic/non-branded unit, ETHEX Corporation, reported fiscal 2008 net revenues of \$367.9 million, an increase of \$132.3 million, or 56.1%, compared to fiscal 2007 net revenues of \$235.6 million; and
- Results for fiscal 2008 were achieved primarily through the approval and launch of the Company's two first-to-file strengths (100 mg and 200 mg) of Metoprolol Succinate Extended-Release Tablets, as well as growth in existing product lines.
- Excluding all Metoprolol sales, ETHEX fiscal 2008 revenues exceeded revenues generated in fiscal 2007 by 5.2%.
- ETHEX revenues contributed 61.1% of KV's consolidated revenues.

\* \* \*

*Product Launches*

\* \* \*

- Metoprolol Succinate Extended-Release Tablets 25 mg (Toprol XL® marketed by AstraZeneca) which since its launch in the final weeks of fiscal 2008 contributed \$0.9 million in incremental net sales. Subsequent to fiscal 2008 year-end, the Company received its ANDA approval on the final strength (50 mg) of Metoprolol Succinate Extended-Release Tablets. While this last approval came later than the Company had expected and delayed contribution of this final strength to net sales until fiscal 2009, the approval of the two additional strengths (25 mg and 50 mg) in addition to the Company's originally first-to-file marketed strengths (100 mg and 200 mg) now enables the Company to market all four strengths of this important product. Through the end of fiscal 2008, net sales contribution from the three marketed strengths of this product was \$120.0 million. The Company expects to see increased revenue contribution from these products throughout fiscal 2009 with the benefit of marketing all four strengths.
- Despite the near-term impact of the removal of a substantial portion of KV's cough/cold products from the ETHEX product line-up and the recent FDA approval of a competitive product entry into the generic Micro-K® marketplace, a substantial product currently marketed by ETHEX, the Company believes ETHEX will continue to post revenue growth during fiscal 2009. Factors which could contribute to fiscal 2009 performance include:
  - Continued revenue contribution from all four strengths of Metoprolol Succinate Extended Release Tablets;
  - Seven ANDA approvals expected during fiscal 2009; and

- An active product development pipeline of more than 50 generic and branded products, which includes both internal development projects, as well as co-development products.

19. Under the heading “*Inventory and Related Charges*” the 4Q08 PR discussed a March 2008 enforcement action by the FDA resulting in an inventory write-off of \$5.5 million. The 4Q08 PR stated in pertinent part as follows:

***Net income for both the fiscal fourth quarter and full fiscal year 2008 included a write-down of \$5.5 million related to inventories of certain cough/cold products previously marketed by ETHEX and subject to the hold initiated by the FDA in March 2008 for which the Company is not pursuing or planning to pursue regulatory approvals due to other higher priority pipeline opportunities. These products generated approximately \$37.6 million in fiscal 2008 sales. In addition, the results include an accrual of \$0.9 million for both the fourth quarter and full year related to the Company’s estimated costs for a recall of certain lots of morphine sulfate 30 mg and 60 mg extended-release tablets. [Emphasis added.]***

20. On or about June 25, 2008, KV filed its delayed December 31, 2007 Form 10-Q (“3Q08 10-Q”) with the SEC, signed by the Individual Defendants. The 3Q08 10-Q, confirmed KV’s previously issued financial results and included the following representations concerning the performance of KV’s generic subsidiary ETHEX and in particular sales of the Company’s cardiovascular drug Metoprolol Succinate. The Form 10-Q stated in pertinent part as follows:

Net revenues for the three months ended December 31, 2007 increased \$43.7 million, or 37.0%, from the prior year quarter as we experienced sales growth of 57.4% in our specialty generics/non-branded products segment. The increase in specialty generic net revenues resulted primarily from the launch in July 2007 of the 100 mg and 200 mg strengths of metoprolol succinate extended-release tablets, the generic version of Toprol-XL(R) (marketed by AstraZeneca). The resulting \$32.1 million increase in consolidated gross profit was offset in part by a \$14.2 million increase in operating expenses. The increase in operating expenses was primarily due to increases in personnel costs, legal fees, research and development expense, and amortization of intangibles. As a result, net income for the third quarter increased \$14.2 million, or 76.6%, to \$32.6 million.

Net revenues for the nine months ended December 31, 2007 increased \$125.8 million, or 38.9%, as we experienced sales growth of 63.0% in our specialty generics/non-branded products segment. The increase in specialty generic net revenues resulted primarily from the launch in July 2007 of the 100 mg and 200 mg strengths of metoprolol succinate extended-release tablets, the generic version of Toprol-XL(R) (marketed by AstraZeneca).

21. Under the heading "Government Regulation" the 3Q08 10-Q included the following representations concerning certain FDA enforcement actions initiated against the Company in March 2008:

In March 2008, representatives of the Missouri Department of Health and Senior Services, accompanied by representatives of the FDA, notified us of a hold on our inventory of certain unapproved drug products, restricting our ability to remove or dispose of those inventories without permission.

*The hold relates to a misinterpretation about the intended scope of recent FDA notices setting limits on the marketing of unapproved guaifenesin products.*

\* \* \*

*The FDA has not proposed, nor do we expect them to propose, that the products subject to the hold be recalled from the distribution channel. As such, we have written-off the value of the products subject to the hold in our inventory as of March 31, 2008. We also evaluated the active pharmaceutical ingredients and excipients used in the manufacture of the hold products and determined that they should also be written-off since we will be discontinuing further manufacturing and many of them cannot be returned or sold to other manufacturers. The write-off included in the results of operations for the fourth quarter of fiscal 2008 totaled \$5.5 million.*

[Emphasis added.]

22. The 3Q08 10-Q also included the following representations concerning certain of ETHEX generic drug recalls initiated during June 2008, stating in pertinent part as follows:

On June 6, 2008, ETHEX initiated a voluntary recall of a single lot of morphine sulfate 60mg extended-release tablets due to a report that a tablet with as much as double the appropriate thickness was identified and therefore the possibility that other oversized tablets could have been commercially released in the affected lot. On June 13, 2008, the recall was expanded to include additional specific lots of morphine sulfate 60 mg extended-release tablets and specific lots of morphine sulfate 30 mg extended release tablets. We accrued a liability of \$0.9 million in the fourth quarter of fiscal 2008 for the anticipated cost of the recall. No oversized tablets have been identified in any additional distributed lot of these products and based on our investigation, there are likely to be few, if any, oversized tablets in the recalled lots. In addition, under ordinary pharmacy dispensing procedures, any significantly oversized tablets would likely be identified at the time of dispensing. However, the decision to recall the additional lots has been taken as a responsible precaution because of the possibility that there may be oversized tablets in the recalled lots.

23. The 3Q08 10-Q further represented that KV's financial statements included therein complied with GAAP in all material respects, stating in pertinent part as follows:

The accompanying unaudited consolidated financial statements of the Company have been prepared in accordance with U.S. Generally Accepted Accounting Principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. However, in the opinion of management, all adjustments (consisting of only normal recurring accruals) considered necessary for a fair presentation have been included.

24. On or about June 26, 2008, KV filed its March 31, 2008 Form 10-K ("2008 10-K") with the SEC, signed by the defendants Hermelin, Kanterman and Chibnall, among others. The 2008 10-K confirmed the Company's previously announced financial results.<sup>4</sup> The 2008 10-K included the following representations concerning KV's compliance with FDA and other regulatory manufacturing practices, stating in pertinent part as follows:

All applications for FDA approval must contain information relating to product formulation, raw material suppliers, stability, manufacturing processes, packaging, labeling and quality control. Information to support the bioequivalence of generic drug products or the safety and effectiveness of new drug products for their intended use is also required to be submitted.

\* \* \*

One requirement for FDA approval of NDAs and ANDAs<sup>5</sup> is that our manufacturing procedures and operations conform to FDA requirements and guidelines, generally referred to as current Good Manufacturing Practices ("cGMP"). The requirements

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<sup>4</sup> The 2008 10-K included substantively identical representations concerning the performance of KV's generics subsidiary, ETHEX, and in particular ETHEX's sales results and sales prospects for its cardiovascular drug Metoprolol Succinate and defendants' representations concerning the March FDA enforcement action and June 2008 drug recall.

<sup>5</sup> New Drug Application ("NDA"). An NDA is filed when approval is sought to market a drug with active ingredients that have not been previously approved by the FDA. NDAs are filed for newly developed brand products and, in certain instances, for a new dosage form, a new delivery system or a new indication for previously approved drugs. Abbreviated New Drug Application ("ANDA"). An ANDA is filed when approval is sought to market a generic equivalent of a drug product previously approved under an NDA.

for FDA approval encompass all aspects of the production process, including validation and recordkeeping, and involve changing and evolving standards.

\* \* \*

We manufacture drug products in liquid, cream, tablet, capsule and caplet forms for distribution by Ther-Rx, ETHEX and our corporate licensees and value-added specialty raw materials for distribution by PDI. ***We believe that all of our facilities are in material compliance with applicable regulatory requirements.***

[Emphasis added.]

25. The 2008 10-K represented that KV's financial statements included therein comply with GAAP in all material respects stating in pertinent part as follows:

The consolidated financial statements that we file with the SEC are prepared in accordance with GAAP. The preparation of financial statements in accordance with GAAP involves making estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses, and the related disclosure of contingent assets and liabilities.

26. On July 29, 2008, KV issued a press release announcing that it was set to dispose of previously written off guaifenesin inventory. The press release stated in pertinent part as follows:

A. LOUIS, July 29 /PRNewswire-FirstCall/ -- KV Pharmaceutical Company(NYSE:KVa/KVb), today reported that it is set to dispose of its inventory of certain drug products -- principally cough/cold products -- previously sold by ETHEX Corporation. The inventory disposal will signal the conclusion of previously disclosed discussions with the FDA regarding the agency's guidance on products containing guaifenesin that were marketed by ETHEX as well as other pharmaceutical companies for a number of years based on long-standing FDA compliance policies.

KV, in the financial statements contained in its fiscal 2008 Form 10-K filed in June 2008, already had written off the value of all the affected products and recognized the financial impact of its decision not to resume the manufacture or sale of those products. Therefore, there will be no further financial impact to KV related to the products to be destroyed.

The final step to resolve the guaifenesin matter is the physical disposal of remaining inventory. In this regard, we have now been informed that the FDA will initially

assume control of the inventory for the purpose of supervising its disposition, procedurally implemented as a “seizure , and then either destroy the products or assign the products back to KV for actual physical destruction. KV will continue its cooperation with the FDA in bringing this matter to final resolution.

27. On August 11, 2008, KV issued a press release announcing its financial results for the first fiscal quarter of 2009 ended June 30, 2008 (“1Q09 PR ). The Company reported that net revenues for the first quarter increased 30.2%, or \$34.5 million, to \$148.9 million, compared with \$114.4 million in the first quarter of fiscal 2008. Gross profits increased 38.6%, or \$28.9 million, to \$103.6 million compared to \$74.8 million in the first quarter of fiscal 2008 and net income for the quarter increased \$6.3 million, or 102.2%, to \$12.5 million, or \$0.23 per diluted Class A common share, compared to \$6.2 million or \$0.12 per diluted Class A common share for the first quarter of fiscal 2008. Defendant Hemerlin commented on KV’s seemingly positive results, stating in pertinent part as follows:

During the first quarter, KV delivered sharply improved profits and nearly \$16.0 million in cash flow from operating activities. Performance was led by strong growth at ETHEX Corporation and continued competitiveness of our category-leading branded products at Ther-Rx. Both of these businesses are poised for further growth over the balance of fiscal 2009 helped by recent introductions like metoprolol succinate extended-release tablets and our branded transdermal spray Evamist . The Company’s pipeline remains strong as well, with expectations of receiving one NDA approval and at least six ANDA approvals during the current fiscal year.

28. In a departure from KV’s previously stated policy, the 1Q09 PR included defendants’ earnings guidance for KV’s fiscal 2009 net revenues and earnings, projecting 8% to 12% growth in net revenues and a 6% to 11% increase in net earnings. The 1Q09 PR stated in pertinent part as follows:

***The Company currently expects to report net revenue of between \$650 million and \$675 million and net income per diluted Class A share of between \$1.65 and \$1.75 for the fiscal year ending March 31, 2009. Although KV historically has not issued revenue or earnings guidance, in light of potential competitive challenges related to certain of the Company’s products, as well as new product launches planned during fiscal 2009 and their potential impact on fiscal 2009 financial performance, we are providing guidance for the current fiscal year. It is not the Company’s***

expectation to further update this guidance during the course of the fiscal year or for future periods.

[Emphasis added.]

29. Under the heading “Subsequent Event” the 1Q09 PR described the recently initiated Audit Committee Investigation into allegations of management misconduct, including defendants’ self-serving denial that it is not aware or does not believe that there has been any misconduct. The 1Q09 PR stated in pertinent part as follows:

***The Company was notified last week that the Audit Committee of its Board of Directors has recently commenced an independent inquiry into allegations made by sources not identified to management regarding alleged misconduct by management of the Company.*** Since 1995, the Company has had in place a Standard of Business Ethics Policy. As part of this policy, an employee is encouraged to report, independent of management and for any reason, any action an employee suspects to be contrary to this code of ethics. Management has not been advised as to the specifics of the allegations and is not in a position to make an informed determination as to whether the allegations have any merit. ***Management is not aware of and does not believe that there has been any misconduct that would have a material impact on the Company’s financial results.*** Management is cooperating fully with the Committee.

[Emphasis added.]

30. On August 11, 2008, KV filed its June 30, 2008 Form 10-Q (“1Q09 10-Q”) with the SEC, signed by the Individual Defendants. The 1Q09 10-Q confirmed the Company’s previously reported financial results and represented that KV’s financial statements included therein complied with GAAP, stating in pertinent part as follows:

The accompanying unaudited consolidated financial statements of the Company have been prepared in accordance with U.S. Generally Accepted Accounting Principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. However, in the opinion of management, all adjustments (consisting of only normal recurring accruals) considered necessary for a fair presentation have been included.

31. The statements referenced above in ¶¶15-30 were each materially false and misleading when made because they failed to disclose and/or misrepresented the following adverse facts, among others:

(a) that KV's manufacturing facilities were in disarray resulting in the manufacture of unsafe drug products that would have to be recalled due to the fact that they may contain oversized tablets. Oversized tablets may contain more than the intended levels of the active drug ingredient, which could result in patients receiving as much as about twice the expected dosage of these drugs;

(b) that KV's management engaged in misconduct by failing to recall the Company's unsafe drug products;

(c) that KV's manufacturing facilities failed to comply with federal regulations including FDA requirements and guidelines, generally referred to as current "Good Manufacturing Practices;

(d) that manufacturing disruptions and inefficiencies were resulting in a material backlog of unshipped customer orders thus further eroding the Company's revenues and earnings;

(e) that the Company failed to write-off at least \$24 million in inventories of discontinued products, seized by the U.S. Attorney for the Eastern District of Missouri due to defendants' violation of FDA enforcement notices;

(f) that KV's post-January 2008 sales of generics were being negatively impacted by material price erosion following the expiration of the Company's exclusive sales period for the drug metoprolol succinate;

(g) that KV's financial statements failed to comply with GAAP; and

(h) that, based on the foregoing, defendants' statements concerning the Company's current and future financial prospects were lacking in a reasonable basis when made and therefore materially false and misleading when made.

### THE TRUTH BEGINS TO EMERGE

32. On or about November 10, 2008, KV issued a press release announcing that it would not file its Form 10-Q for the quarter ended September 30, 2008 due to its Audit Committee's continuing investigation into allegations of management misconduct. The press release stated in pertinent part as follows:

ST. LOUIS, Nov. 10 /PRNewswire-FirstCall/ -- KV Pharmaceutical Company (NYSE:KVa/KVb ) announced today that due to the ongoing Audit Committee inquiry previously announced, the Company will be delayed in the filing of its Form 10-Q for the second quarter of fiscal 2009. The Company expects to file a Form 12b-25 Notice of Late Filing with the Securities and Exchange Commission on Wednesday, November 12, 2008.

33. Then on November 13, 2008, KV announced that it is unable to file its Form 10-Q for the quarter ended September 30, 2008 due to a continuing investigation by the Company's Audit Committee into allegations of management misconduct concerning recalls of the Company's drug products. KV's notice its late filing with the SEC on Form 12b-25 stating in pertinent part as follows:

...the Audit Committee of K-V Pharmaceutical Company (the "Company" or "KV"), with the assistance of legal counsel, including FDA regulatory counsel, and other advisors, is **conducting an internal investigation with respect to a range of specific allegations, from multiple sources, involving, among other items, FDA regulatory and other compliance matters and management misconduct. One previously announced FDA recall of a Company product is associated with the investigation as are two new recalls involving several products dated November 7 and November 10, 2008.** The Audit Committee presently intends to complete its investigation, deliver its findings and issue its recommended remedial actions before the end of December 2008. The timing of the review delayed the filing of the Company's Form 10-Q for the quarter ended September 30, 2008.

[Emphasis added.]

This shocking news was accompanied by additional adverse news concerning the Company's earnings and future prospects:

- **108% decline in Net Earnings** – The Company reported an *estimated loss of \$0.06 per share* for the second quarter of 2009, a Y-Y decline of \$0.76 per share or 108% compared to the prior year. The Company's *gross profits declined 11%* driven by declines at Ethex (-9.1%). As a result of the Audit Committee Investigation, KPMG, KV's outside auditor, could not complete their review of the Company's second quarter financials and therefore all amounts are estimated subject to the KPMG review being completed. The Company also announced
- **16% decline in Y-Y 2nd Quarter Revenues** – Defendants announced that second quarter 2009 net revenues declined 16% (\$28 million) compared to the same quarter last year. Ethex revenues declined \$20 million due in part to guaifenesin/hydrocortisone product discontinuations (\$7.0 million) and \$18 million in unshipped orders resulting from "manufacturing interruptions and inefficiencies.
- **\$6.5 Million in Additional Loss Reserves** – Defendants announced that KV had incurred at least \$1.3 million in legal costs related to the Audit Committee Investigation and an additional \$5.2 million in estimated reserves for product recalls
- **Withdrawal of 2009 Guidance** – Defendants announced that they were withdrawing KV's previously issued revenue and earnings guidance for fiscal 2009. In August, 2008, defendants had taken the extraordinary step of departing from KV's previous practice of not issuing guidance to the market by including revenue and earnings guidance for 2009 in its press release announcing preliminary second quarter fiscal 2009. Defendants' August 2008 projections of an 8 to 12% increase in 2009 net revenues and a 6-11% increase in earnings were false when made. The guidance came on the heels of KV's announcement that its Audit Committee was investigating management misconduct.

34. Following these November 13th statements the price of KV common stock fell nearly 59% from \$14.26 per share to \$5.90 per share on extremely heavy volume of more than 6.6 million shares, thirty-three times the stock's average trading volume.

#### SCIENTER

35. During the Class Period, the defendants had both the motive and opportunity to conduct fraud. They also had actual knowledge of the misleading nature of the statements they made or acted in reckless disregard of the true information known to them at the time. In so doing, the defendants participated in a scheme to defraud and committed acts, practices and participated in a

course of business that operated as a fraud or deceit on purchasers of KV stock during the Class Period.

### **LOSS CAUSATION/ECONOMIC LOSS**

36. During the Class Period, as detailed herein, defendants made false and misleading statements and engaged in a scheme to deceive the market and a course of conduct that artificially inflated the price of KV securities and operated as a fraud or deceit on Class Period purchasers of KV securities by misrepresenting the Company's business. Later, when defendants' prior misrepresentations and fraudulent conduct became apparent to the market, the price of KV securities fell precipitously, as the prior artificial inflation came out of the price. As a result of their purchases of KV securities during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

### **NO SAFE HARBOR**

37. KV's verbal "Safe Harbor" warnings accompanying its oral forward-looking statements ("FLS") issued during the Class Period were ineffective to shield those statements from liability.

38. The defendants are also liable for any false FLS pleaded because, at the time each FLS was made, the speaker knew the FLS was false and the FLS was authorized and/or approved by an executive officer of KV who knew that the FLS was false. None of the historic or present tense statements made by defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance, as they were not stated to be such assumptions underlying or relating to any projection or statement of future economic performance when made, nor were any of the projections or forecasts made by defendants expressly related to or stated to be dependent on those historic or present tense statements when made.

**APPLICABILITY OF PRESUMPTION OF  
RELIANCE: FRAUD ON THE MARKET**

39. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) The omissions and misrepresentations were material;

(c) The Company's stock traded in an efficient market;

(d) The misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's stock; and

(e) Plaintiff and other members of the Class purchased KV stock between the time defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

40. At all relevant times, the markets for KV stock were efficient for the following reasons, among others:

(a) As a regulated issuer, KV filed periodic public reports with the Securities and Exchange Commission;

(b) KV regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases on the major news wire services and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts and other similar reporting services; and

(c) KV common stock was actively traded in an efficient market, namely the NYSE, under the symbol KVA.

### CLASS ACTION ALLEGATIONS

41. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased KV stock during the Class Period (the “Class”). Excluded from the Class are defendants, directors and officers of KV and their families and affiliates.

42. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. KV had more than 49 million shares of stock outstanding, owned by thousands of persons.

43. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) Whether the 1934 Act was violated by defendants;
- (b) Whether defendants omitted and/or misrepresented material facts;
- (c) Whether defendants’ statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (d) Whether defendants knew or recklessly disregarded that their statements were false and misleading;
- (e) Whether the prices of KV stock were artificially inflated; and
- (f) The extent of damage sustained by Class members and the appropriate measure of damages.

44. Plaintiff’s claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants’ wrongful conduct.

45. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

46. A class action is superior to other available methods for the fair and efficient adjudication of this controversy.

## COUNT I

### **For Violation of §10(b) of the 1934 Act and Rule 10b-5 Against All Defendants**

47. Plaintiff incorporates ¶¶1-46 by reference.

48. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or recklessly disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

49. Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they:

- (a) Employed devices, schemes, and artifices to defraud;
- (b) Made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or
- (c) Engaged in acts, practices, and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of KV stock during the Class Period.

50. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for KV stock. Plaintiff and the Class would not have purchased KV stock at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

51. As a direct and proximate result of these defendants' wrongful conduct, plaintiff and the other members of the Class suffered damages in connection with their purchases of KV stock during the Class Period.

## **COUNT II**

### **For Violation of §20(a) of the 1934 Act Against All Defendants**

52. Plaintiff incorporates ¶¶1-51 by reference.

53. The Individual Defendants acted as controlling persons of KV within the meaning of §20(a) of the 1934 Act. By virtue of their positions and their power to control public statements about KV, the Individual Defendants had the power and ability to control the actions of KV and its employees. KV controlled the Individual Defendants and its other officers and employees. By reason of such conduct, defendants are liable pursuant to §20(a) of the 1934 Act.

## **PRAYER FOR RELIEF**

WHEREFORE, plaintiff prays for judgment as follows:

- A. Declaring this action to be a proper class action pursuant to Fed. R. Civ. P. 23;
- B. Awarding plaintiff and the members of the Class damages and interest;
- C. Awarding plaintiff's reasonable costs, including attorneys' fees; and
- D. Awarding such equitable/injunctive or other relief as the Court may deem just and proper.

## **JURY DEMAND**

Plaintiff demands a trial by jury.

DATED: December 2, 2008