

VIROPHARMA INC

FORM 8-K

(Current report filing)

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Address	730 STOCKTON DRIVE EXTON, PA 19341
Telephone	6104587300
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**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): April 9, 2012

V I R O P H A R M A I N C O R P O R A T E D

(Exact Name of Registrant as Specified in its Charter)

DELAWARE
(State or Other Jurisdiction of
Incorporation or Organization)

0-021699
(Commission
File Number)

23-2789550
(I.R.S. Employer
Identification Number)

730 STOCKTON DRIVE, EXTON, PENNSYLVANIA
(Address of Principal Executive Offices)

19341
(Zip Code)

(610) 458-7300
(Registrant's Telephone Number, Including Area Code)

Check the appropriate box below if the Form 8-K is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act
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Item 8.01. Other Events.

ViroPharma Incorporated (the “Company”) today announced that on April 9, 2012, the U.S. Food and Drug Administration (FDA) denied the Citizens Petition (Docket # FDA-2006-P-0007) filed by ViroPharma on March 17, 2006 related to the FDA’s proposed in-vitro method for determining bioequivalence of abbreviated new drug applications (ANDAs) of Vancocin® (vancomycin hydrochloride, USP) Capsules. In the FDA’s response to the citizen’s petition, the agency dismissed all scientific and legal questions raised by ViroPharma and also informed the company that a final guidance for vancomycin bioequivalence consistent with the FDA’s citizen petition response is forthcoming. FDA also indicated that it is approving three ANDA’s for generic vancomycin capsules.

The FDA also informed ViroPharma in the same correspondence that the recent sNDA for Vancocin from December 14, 2011 would not qualify for three additional years of exclusivity based on the agency’s narrow interpretation of the statutory authority to require a “significant new usage” or new indications for, an old antibiotic (such as Vancocin) in order for a sNDA to be eligible for a grant of exclusivity.

ViroPharma intends to file a complaint in the United States District Court for the District of Columbia, seeking an injunction to enjoin the FDA’s approval of ANDAs for generic versions of Vancocin.

In addition, the company has received a notification that the Federal Trade Commission is conducting an investigation into whether the company has engaged in unfair methods of competition with respect to Vancocin. The existence of an investigation does not indicate that the FTC has concluded that ViroPharma has violated the law and the company does not believe that it has engaged in unfair methods of competition with respect to Vancocin. The Company intends to cooperate with the FTC investigation.

The full text of a press release issued by the Company in connection with the announcement is set forth as Exhibit 99.1 attached hereto.

Item 9.01 Financial Statements and Exhibits.

The following exhibits are attached to this Form 8-K:

	<u>Exhibit</u>	<u>Description</u>
(d)	<u>No.</u>	
	99.1	Press release dated April 10, 2012.

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.

V I R O P H A R M A I N C O R P O R A T E D

Date: April 10, 2012

By: /s/ J. Peter Wolf

J. Peter Wolf

Vice President, General Counsel and Secretary

Index of Exhibits

<u>Exhibit Number</u>	<u>Description</u>
99.1	Press release dated April 10, 2012.



V I R O P H A R M A I N C O R P O R A T E D Contact:
 Robert A. Doody
 Assistant Director, Investor Relations
 Phone (610) 321-6290

VIROPHARMA PROVIDES UPDATE ON STATUS OF CITIZEN PETITION REGARDING BIOEQUIVALENCE AND EXCLUSIVITY FOR VANCOCIN® (VANCOMYCIN HYDROCHLORIDE, USP) CAPSULES

Exton, PA, April 10, 2012 — ViroPharma Incorporated (Nasdaq: VPHM) today announced the U.S. Food and Drug Administration (FDA) denied the citizen petition (Docket # FDA-2006-P-0007) filed by ViroPharma on March 17, 2006 related to the FDA's proposed in vitro method for determining bioequivalence of abbreviated new drug applications (ANDAs) referencing Vancocin® (vancomycin hydrochloride, USP) Capsules. In the FDA's response to the citizen petition, the agency denied ViroPharma's citizen petition and also informed the company that a final guidance for vancomycin bioequivalence consistent with the FDA's citizen petition response is forthcoming.

The FDA also informed ViroPharma in the same correspondence that the recent supplemental new drug application (sNDA) for Vancocin approved December 14, 2011 would not qualify for three additional years of exclusivity based on the agency's assertion that in order for an sNDA for an old antibiotic such as Vancocin to be eligible for a grant of exclusivity, it must be a significant new use or indication. FDA also indicated that it is approving three ANDA's for generic vancomycin capsules. The FDA has posted the citizen petition response at <http://www.regulations.gov#!documentDetail;D=FDA-2006-P-0007-0051>.

ViroPharma intends to file a complaint in the United States District Court for the District of Columbia, seeking an injunction to set aside the FDA's approval of ANDA's for generic versions of Vancocin. While the courts dismissed ViroPharma's prior lawsuit on the procedural basis of standing, the substance of the company's bioequivalence arguments and the arguments regarding Vancocin's eligibility for exclusivity have not been litigated before the Court.

As it has since 2006, the company will actively pursue a legal remedy in these matters in order to ensure the safety of patients. ViroPharma's efforts to date have already helped make FDA's approval standards for generic vancomycin capsules more patient-protective. FDA's 2006 in vitro bioequivalence method did not protect patients from the risks of inactive ingredient differences, but after ViroPharma filed its petition FDA in 2008 determined that generic products would not be eligible for the in vitro method unless they have the same inactive ingredients in the same quantities as Vancocin. And in yesterday's petition response FDA further tightened the standards to require that generics use a particular grade of polyethylene glycol.

ViroPharma believes that FDA is incorrect in interpreting its bioequivalence regulations in a manner that provides it with broad discretion to permit in vitro bioequivalence testing in the absence of a waiver of in vivo testing. ViroPharma believes that the FDA's position is not supported by its regulations, or by FDA's stated interpretation of those regulations at the time of their enactment.

Moreover, ViroPharma believes that the three year exclusivity provisions for old antibiotics were intended to incent “clinically relevant new safety and efficacy information” (as FDA described the new Vancocin information in its letter approving the recent sNDA) concerning the appropriate use of old antibiotics, particularly where the label for such a product contained no such information, because new prescribing instructions for physicians based on data in modern microbial strains will result in better care for patients. ViroPharma believes that narrowly construing the exclusivity provision will likely dissuade manufacturers from these types of investments in better patient care with old antibiotics and is inconsistent with the statute and Congressional intent for older antibiotics.

The company will provide an update to total company and Vancocin net sales guidance no later than in conjunction with the financial results of the first quarter of 2012 expected on or about May 1, 2012.

In addition, the company has received a notification that the Federal Trade Commission is conducting an investigation into whether the company has engaged in unfair methods of competition with respect to Vancocin. The existence of an investigation does not indicate that the FTC has concluded that ViroPharma has violated the law and the company does not believe that it has engaged in unfair methods of competition with respect to Vancocin. The company intends to cooperate with the FTC investigation.

Conference Call and Webcast

ViroPharma is hosting a live teleconference and webcast with senior management to discuss this announcement this morning at 9:30 a.m. Eastern. To participate in the conference call, please dial (800) 275-6556 (domestic) and (302) 607-2010 (international). After placing the call, please tell the operator you wish to join the ViroPharma investor conference call.

Alternatively, the live webcast of the conference call can be accessed via ViroPharma’s website at <http://www.viropharma.com>. Windows Media or Real Player will be needed to access the webcast. An audio archive will be available at the same address until April 30, 2012.

About Vancocin® (vancomycin hydrochloride, USP) Capsules

Vancocin is indicated for the treatment of *C. difficile*- associated diarrhea (CDAD). Vancocin is also used for the treatment of enterocolitis caused by *Staphylococcus aureus* (including methicillin-resistant strains). Vancocin is contraindicated in patients who have experienced a hypersensitivity to vancomycin. Vancocin must be given orally for treatment of staphylococcal enterocolitis and CDAD. Orally administered Vancocin is not effective for other types of infections. Clinically significant serum concentrations have been reported in some patients who have taken multiple oral doses of Vancocin for active CDAD. Monitoring of serum concentrations may be appropriate in some instances.

Nephrotoxicity has occurred following oral Vancocin therapy and can occur either during or after completion of therapy. The risk is increased in geriatric patients. Monitor renal function. Ototoxicity has occurred in patients receiving Vancocin. Assessment of auditory function may be appropriate in some instances. Prescribing Vancocin in the absence of a proven or strongly suspected bacterial infection is unlikely to provide benefit to the patient and increases the risk of the development of drug resistant bacteria. In clinical trials, the most common adverse reactions (greater than or equal to 10 percent) were nausea (17 percent), abdominal pain (15 percent), and hypokalemia (13 percent). Patients over 65 years of age may take longer to respond to therapy compared to patients less than 65 years of age. Clinicians should be aware of the importance of appropriate duration of Vancocin treatment in patients over 65 years of age and not discontinue or switch to alternative treatment prematurely.

For Vancocin prescribing information, please visit <http://www.viropharma.com/products/vancocin.aspx>

About ViroPharma Incorporated

ViroPharma Incorporated is an international biopharmaceutical company committed to developing and commercializing novel solutions for physician specialists to address unmet medical needs of patients living with diseases that have few if any clinical therapeutic options, including C1 esterase inhibitor deficiency, treatment of seizures in children and adolescents, adrenal insufficiency, and *C. difficile* -associated diarrhea (CDAD). Our goal is to provide rewarding careers to employees, to create new standards of care in the way serious diseases are treated, and to build international partnerships with the patients, advocates, and health care professionals we serve. ViroPharma's commercial products address diseases including hereditary angioedema (HAE), seizures in children and adolescents, and CDAD; for full U.S. prescribing information on our products, please download the package inserts at <http://www.viropharma.com/Products.aspx>; the prescribing information for other countries can be found at www.viropharma.com.

ViroPharma routinely posts information, including press releases, which may be important to investors in the investor relations and media sections of our company's web site, www.viropharma.com. The company encourages investors to consult these sections for more information on ViroPharma and our business.

ViroPharma Forward Looking Statements

Certain statements in this press release contain forward-looking statements that involve a number of risks and uncertainties. Forward-looking statements provide our current expectations or forecasts of future events, including our beliefs that FDA is incorrect in interpreting its bioequivalence regulations in a manner that provides it with broad discretion to permit in vitro bioequivalence testing in the absence of a waiver of in vivo testing, that FDA's position is not supported by its regulations, that the FDA interpretation of the three year statutory exclusivity provisions are too narrow, our ability to provide updated sales guidance in the in the timeframe that we anticipate and that the company does not believe that it has engaged in unfair methods of competition. There can be no assurance that the U.S. District Court will agree with our views that the bioequivalence regulations require the issuance of a bioequivalence waiver or that Vancocin meets the statutory requirements for three years of exclusivity. In the event that the US District Court does not agree with our positions, the entry of competing generic products will significantly affect our sales of Vancocin and our financial performance. In addition, the notice of the FTC investigation did not specify the nature of unfair methods of competition they are investigating therefore the scope and outcome of the investigation are uncertain. Our ability to provide updated sales guidance is dependent in part upon the timing and outcomes of the litigation described in this press release. These factors, and other factors, including, but not limited to those described in our annual report on Form 10-K for the year ended December 31, 2011, could cause future results to differ materially from the expectations expressed in this press release. The forward-looking statements contained in this press release are made as of the date hereof and may become outdated over time. ViroPharma does not assume any responsibility for updating any forward-looking statements. These forward looking statements should not be relied upon as representing our assessments as of any date subsequent to the date of this press release.

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