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EPIX Pharmaceuticals, Inc. Form 8-K June 19, 2007

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): <u>June 15, 2007</u> <u>EPIX Pharmaceuticals, Inc.</u>

(Exact Name of Registrant as Specified in its Charter) **Delaware**

(State or Other Jurisdiction of Incorporation)

000-21863 04-3030815

(Commission File Number)

(IRS Employer Identification No.)

4 Maguire Road, Lexington, Massachusetts

02421

(Address of Principal Executive Offices)

(Zip Code)

Registrant s telephone number, including area code: (781) 761-7600

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))

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EX-99.1 Press Release dated June 18, 2007

Item 7.01 Regulation FD Disclosure.

On June 18, 2007, EPIX Pharmaceuticals, Inc. (EPIX) issued a press release, a copy of which is being furnished as Exhibit 99.1 to this Report on Form 8-K.

The information in this Item 7.01 and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934 (the Exchange Act) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as expressly set forth by specific reference in such filing. **Item 8.01 Other Events.**

On June 15, 2007, EPIX received a letter from the U.S. Food and Drug Administration (FDA) regarding EPIX s formal appeal with the FDA asking the FDA to approve its blood-pool imaging agent, Vasovist, and to convene an advisory committee if more advice on approvability of Vasovist was required. Although the FDA denied the appeal, it indicated that a blinded re-read, or reanalysis, of the images obtained in EPIX s previously completed Phase 3 clinical trials of Vasovist could provide the potential core of the evidence to support approval of Vasovist if the results of the re-read are positive and that further clinical trials may not be necessary. In its response, the FDA strongly recommended that EPIX work closely with the FDA to develop the appropriate protocol for the re-read, including how the reading will be done, how the data from the re-reading will be analyzed and a plan for statistical analysis, prior to conducting a re-read of the images. Once any re-read process and analysis is completed, EPIX will be required to submit an amendment to its new drug application for Vasovist to the FDA. The approval, timeliness of approval or labeling of Vasovist remain subject to significant uncertainties related to a number of factors, including the process of reaching agreement with the FDA on the protocols required for a re-read of the images obtained from completed Phase 3 trials, obtaining the desired results of such re-read of images by a new group of radiologists and the FDA s review process and conclusions regarding any additional Vasovist regulatory submissions.

Item 9.01 Financial Statements and Exhibits.

- (d) Exhibits:
- 99.1 Press Release issued by the registrant on June 18, 2007, furnished 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.

EPIX PHARMACEUTICALS, INC.

June 18, 2007 By: /s/ Kim C. Drapkin

Kim C. Drapkin

Chief Financial Officer

EXHIBIT INDEX

Exhibit Number Description

99.1 Press Release issued by the registrant on June 18, 2007, furnished herewith.