

EPIX Pharmaceuticals, Inc.
Form 8-K
November 01, 2005

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**

WASHINGTON, DC 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): November 1, 2005

EPIX Pharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Its Charter)

Delaware

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(State or Other Jurisdiction of Incorporation)

000-21863

(Commission File Number)

04-3030815

(IRS Employer Identification No.)

161 First Street, Cambridge, Massachusetts 02142

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(Address of Principal Executive Offices)

(Zip Code)

(617) 250-6000

(Registrant's Telephone Number, Including Area Code)

(Former Name or Former Address, if Changed Since Last Report)

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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Item 2.02. Results of Operations and Financial Condition.

On November 1, 2005, EPIX Pharmaceuticals, Inc. issued a press release that announced its financial results for the third quarter ended September 30, 2005. A copy of the press release is attached to this Current Report on Form 8-K as Exhibit 99.1 and is incorporated herein by reference. In addition, the following is an excerpt from the remarks of Michael Astrue, Interim Chief Executive Officer, in the script for the conference call relating to the financial results for the third quarter:

As you might imagine, a great deal of my time over the last six weeks has been spent on understanding the status of the Vasovist review at the FDA. We continue to believe that the Company's four Phase III studies provide a more than adequate basis for approval, an opinion which we believe is validated by our recent routine approval in the European Union. During the last six weeks, we have tried to open new channels of communication with the FDA, and have made it as clear as we can to the agency that we are extremely open to any and all discussions about our submission. To date, however, and despite several conversations both with our line reviewer and with his superiors in the organization, we do not have any more clarity beyond what was provided in the original, so-called "approvable" letter of January 2005. In our conversations the FDA has made it a point to state that it has not completed its review and that it has not made its decision on whether or not to approve Vasovist. They have also indicated that they are on schedule for the November 23 PDUFA date. Notwithstanding this information, it is our sense, both from the absence of scientific dialogue and the pattern of questions we have received that the FDA is unlikely to approve Vasovist without a reread or an additional study.

Now, let me be clear in telling you that there has been no verbal or written communication from the FDA that compels this conclusion. And, in fact, if you were to read transcripts of the calls that we have had, you would not necessarily come to this conclusion, since the words themselves are neutral. But, in the spirit of transparency, I believe we should share our general impression of the tone and tenor of the conversations.

This information shall not be deemed to be filed for the purposes of Section 18 of the Securities and Exchange Act of 1934 (the Exchange Act) and shall not 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 a filing.

Item 9.01. Financial Statements and Exhibits.

(d) The following exhibits are furnished with this report:

Exhibit Number	Description
99.1	Press Release dated November 1, 2005.

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.

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(Registrant)

Date: November 1, 2005

/s/

Michael J. Astrue
Michael J. Astrue
Interim Chief Executive Officer

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