

Anthera Pharmaceuticals Inc
Form 8-K
November 16, 2010

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): November 16, 2010
ANTHERA PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware

001-34637

20-1852016

(State or other jurisdiction of
incorporation)

(Commission File Number)

(I.R.S. Employer
Identification No.)

25801 Industrial Boulevard, Suite B, Hayward,
California

94545

(Address of principal executive offices)

(Zip Code)

Registrant's telephone number, including area code: (510) 856-5600

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:

- 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 8.01 Other Events.

On November 16, 2010, Anthera Pharmaceuticals, Inc. (the Company) issued a press release announcing that it had notified the U.S. Food and Drug Administration that the Company has placed a voluntary hold on PEARL-SC, the Phase 2b study of A-623 for the treatment of Systemic Lupus Erythematosus, due to problems found with its product vials. The Company was recently notified by a single clinical investigator that a number of vials of clinical product had experienced structural failure (cracking). After a preliminary inspection of selected product inventory at the site and at a product storage facility, the Company determined on the evening of November 15, 2010, that the single site finding was not an isolated problem. As a result of these findings, patient enrollment in the PEARL-SC study was immediately suspended and patients currently enrolled in the study will discontinue dosing while the Company conducts a complete analysis of the problem. There have been no reports of patient-related side effects or problems with drug administration that could be attributed to this problem and to date, no serious adverse events have been reported to the Company in the PEARL-SC trial.

A copy of the press release is filed herewith as Exhibit 99.1.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release, dated November 16, 2010

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.

Date: November 16, 2010

Anthera Pharmaceuticals, Inc.

By: /s/ Christopher P. Lowe
Christopher P. Lowe
Chief Financial Officer and
Vice President of Administration

Exhibit Index

Exhibit No.	Description
99.1	Press Release, dated November 16, 2010