MAP Pharmaceuticals, Inc.
Form 8-K
June 25, 2012

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): June 25, 2012

MAP PHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-33719**	**20-0507047**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

2400 Bayshore Parkway, Suite 200, Mountain

View, CA **94043**
(Address of Principal Executive Offices) **(Zip Code)**
Registrant s telephone number, including area code: (650) 386-3100

(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):

¨ 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))

Item 8.01. Other Events.

In a press release issued on June 25, 2012, MAP Pharmaceuticals, Inc. (the Company) provided an update regarding the meeting held with the U.S. Food and Drug Administration (FDA) to discuss the Complete Response Letter to the Company s New Drug Application for LEVADEX (dihydroergotamine) inhalation aerosol.

Based on the meeting with the FDA, the Company believes that it has clarity on what is needed to address the issues in the Complete Response letter and plans to resubmit to the FDA in the late third quarter/early fourth quarter 2012 timeframe.

Based on the meeting, the Company believes that no new studies need to be conducted for inclusion in the resubmission. The FDA will determine the type of resubmission (Class 1 or Class 2) and the resulting review timeline after the resubmission has been accepted for filing.

In the CRL, the FDA requested that the Company address issues relating to chemistry, manufacturing and controls (CMC) and observations from a facility inspection of a third party manufacturer. The FDA also indicated that it had not been able to complete review of inhaler usability information requested late in the review cycle by the FDA.

The CMC issues are focused on commercial product specifications and justification of process controls to reflect the product specifications. The Company believes it has all data necessary to respond and confirmed at the FDA meeting its approach to address these issues. The FDA also agreed with the Company s proposal to include recently completed 24 month stability data on LEVADEX in the resubmission.

The FDA provided clarity on the steps necessary for the Company s third party manufacturer to address observations related to the implementation and documentation of manufacturing process controls cited during a facility inspection. The Company is working closely with its third party manufacturer. The third party manufacturer provided responses to the observations to the FDA, and the Company believes the observations cited by the FDA either have been resolved or will be addressed in conjunction with the resubmission.

With respect to inhaler usability information, the FDA has requested that the Company provide information on patient experience related to inhaler usability from the existing clinical data set to augment the information previously provided. The Company believes it has the data necessary to provide this additional information.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of MAP Pharmaceuticals, Inc., dated June 25, 2012.

SIGNATURE

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: June 25, 2012

MAP PHARMACEUTICALS, INC.

By: /s/ Charlene A. Friedman
Name: Charlene A. Friedman
Title: Senior Vice President, General Counsel and Secretary

INDEX TO EXHIBITS FILED WITH

THE CURRENT REPORT ON FORM 8-K DATED JUNE 25, 2012

Exhibit No.	Description
99.1	Press Release of MAP Pharmaceuticals, Inc., dated June 25, 2012