AMAG PHARMACEUTICALS INC.
Form 8-K
March 17, 2008

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): **March 17, 2008**

AMAG PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation)

0-14732	**04-2742593**
(Commission File Number)	(IRS Employer Identification No.)
125 CambridgePark Drive **Cambridge, Massachusetts**	**02140**
(Address of principal executive offices)	(Zip Code)

(617) 498-3300

(Registrant s telephone number, including area code)

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))

Item 8.01. Other Events

On March 17, 2008, at the Cowen and Company 28th Annual Health Care Conference, AMAG Pharmaceuticals, Inc., or the Company, intends to announce that in February 2008 it held what it believes was a successful New Drug Application, or NDA, orientation presentation to the Reviewing Division of the U.S. Food and Drug Administration, or the FDA, with respect to its submission seeking marketing approval for ferumoxytol as an intravenous iron replacement therapeutic in chronic kidney disease patients.

Orientation presentations such as this are a relatively new routine process which is optional and is initiated by the FDA to obtain an overview of a submitted NDA after it has been filed. Companies have the opportunity to meet with the FDA for approximately 90 minutes to review the NDA submission and highlight issues that they deem relevant and key aspects of the filing, including product attributes, efficacy and safety results and any other issue considered important with the agency. During the orientation presentation, the FDA has an opportunity to ask questions with respect to the NDA.

Additionally, on March 17, 2008, at the Cowen Conference, the Company expects to reiterate its intention to conduct a Phase III clinical development program for ferumoxytol as a treatment for patients suffering from abnormal uterine bleeding, or AUB, in mid 2008. The objective of this program will be to demonstrate the safety and efficacy of ferumoxytol in women with iron deficiency anemia, or IDA, and AUB. It is expected that this program will involve 500 to 700 subjects. The program design is currently being discussed with the FDA.

The Company also expects to announce its intention to conduct a broad Phase III clinical development program in patients with IDA resulting from multiple causes, including cancer, to begin in the second half of 2008. The objective of this program will be to demonstrate the safety and efficacy of ferumoxytol in subjects who have IDA resulting from multiple causes, including both chemotherapy-induced anemia and anemia of cancer. The particular design of this program is under development and is subject to further discussions with the FDA.

This report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and other federal securities laws. Any statements contained herein that do not describe historical facts, including but not limited to, statements regarding our potential development of ferumoxytol for use in the areas of abnormal uterine bleeding, iron deficiency anemia and other new indications, are forward-looking statements that involve risks and uncertainties that could cause actual results to differ materially from those discussed in such forward-looking statements. Such risks and uncertainties include the following:

(1) the possibility that we may not be able to obtain the necessary regulatory approvals in order to market and sell ferumoxytol, or we may not obtain such approvals in a timely manner due to deficiencies in the design or oversight by us of these trials, the failure of our trials to demonstrate that ferumoxytol is safe and efficacious, or any other factor causing an increase in expenses, a delay and/or a negative effect on the results of the clinical studies or the prospects of regulatory approval for ferumoxytol; (2) the fact that we have limited sales and marketing

expertise; (3) uncertainties regarding our ability to successfully compete in the intravenous iron replacement market; (4) uncertainties regarding our ability to obtain favorable coverage, pricing and reimbursement for ferumoxytol, if approved; (5) uncertainties regarding our ability to manufacture sufficient quantities of ferumoxytol to meet demand, if approved; (6) uncertainties relating to our patents and proprietary rights; and (7) other risks identified in our Securities and Exchange Commission filings.

We caution you not to place undue reliance on any forward-looking statements which speak only as of the date they are made. We disclaim any obligation to publicly update or revise any such statements to reflect any change in expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

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 thereunto duly authorized.

AMAG PHARMACEUTICALS, INC.

By: /s/ Joseph L. Farmer

Joseph L. Farmer
General Counsel and Vice President of Legal Affairs

Date: March 17, 2008