AMAG PHARMACEUTICALS INC. Form 8-K October 20, 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): October 20, 2008

# AMAG PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

#### Delaware

(State or other jurisdiction of incorporation)

**0-14732** (Commission File Number)

**04-2742593** (IRS Employer Identification No.)

100 Hayden Ave Lexington, Massachusetts (Address of principal executive offices)

**02421** (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 ur the following provisions:	nder any of
" 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	l-2(b))
" Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e	-4(c))

Item 7.01 Regulation FD Disclosure
AMAG Pharmaceuticals, Inc. (the Company ) today announced that it has received a complete response letter from the U.S. Food and Drug Administration (FDA) for ferumoxytol for the treatment of iron deficiency anemia in chronic kidney disease patients.
The Company submitted its New Drug Application for marketing approval of ferumoxytol in December 2007.
The Company believes that it can address the issues raised by the FDA in its complete response letter in a timely and expeditious manner without conducting any additional clinical trials prior to approval, including any clinical trials with respect to repeat courses of ferumoxytol or long-term follow-up of patients receiving ferumoxytol. In addition, the Company continues preparations for the intended commercial launch of ferumoxytol during the first quarter of 2009. The Company continues to seek approval of ferumoxytol for the treatment of iron deficiency anemia in patients with chronic kidney disease, whether or not on dialysis.
The Company is continuing to evaluate the impact of the complete response letter on the timing of its other planned clinical development programs for ferumoxytol.
The full text of this press release is attached as Exhibit 99.1 hereto and is incorporated by reference herein.
Item 9.01. Financial Statements and Exhibits.
(d) Exhibits.
The Company hereby files the following exhibit:
99.1 Press Release dated October 20, 2008.

#### **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 Senior Vice President of Legal Affairs

Date: October 20, 2008

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### EXHIBIT INDEX

Exhibit Number Description

99.1 Company Press Release Dated October 20, 2008

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